EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY

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I hereby declare that the thesis entitled "**EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY**" submitted towards partial fulfillment of the requirements for the award of **MS in SURGERY** degree to BFUHS is a compilation of original work carried out by me under the supervision of Dr Jaspal Singh, Professor & Head and Dr. Sanjeev Singla, Professor, Department of General Surgery. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated
to
my
Family
&
Teachers

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Dr. Anubhavv Gupta

LIST OF ABBREVIATIONS

LC	Laparoscopic Cholecystectomy
SAGES	Society of Americal Gastrointestinal and Endoscopic surgeons
BDI	Bile duct injury
NIR	Near Infrared Imaging
ERCP	Endoscopic Retrograde cholangiopancreatography
IOC	Intra-operative cholangiography
ICG	Indocyanine Green
CBD	Common Bile duct
RPHD	Right posterior hepatic duct
CHD	Common hepatic duct
SNR	Signal to noise ratio
NIRC	Near infrared imaging cholangiography
GA	General Anaesthesia

ABSTRACT

Introduction: An observational study to evaluate the role of intra-operative cholangiography using Indocyanine green dye during Laparoscopic cholecystectomy.

Aim of study: To study the feasibility and safety of using ICG during Lap. Cholecystectomy, the post-operative outcome in these patients and the timing of said dye administration pre-operatively.

Materials and methods: An observational study was conducted at Dayanand medical college and hospital, Ludhiana from July 2020 to Decenber 2021 in which 71 patients underwent Lap. Cholecystectomy with NIR-ICG cholangiography. One patient was not administered the dye in view of a history of iodine allergy.

Results: 71 patients were included in the study, with age ranging between 18 and 84 years with a mean age of 48.2 years with a female predominance in the study subjects with 66.2 % females. The mean duration of surgery was 58.10 minutes and all the subjects were administered the dye 15 to 60 minutes prior to surgery (88.6% at 30 minutes before surgery). Higher rates of non-visualization of CBD and CD were observed with cases with more inflammatory changes (acute cholecystitis, empyema GB and biliary pancreatitis). The mean time of GB visualization was 32.45 minutes, CD visualization was 32.10 minutes and that of CBD was 26.33 minutes. One patient had a class E2 injury during the procedure, which was then converted to open. One patient had a subcapsular liver hematoma, which was managed conservatively.

Conclusion: Near infrared imaging based intra-operative cholangiography using ICG during Lap. Cholecystectomy is a useful method of visualizing the biliary ductal anatomy and its variation during the surgery and in thus helping to prevent injury to the CBD. We also observed that the CBD and cystic duct were not clearly visualized on NIR-ICG IOC in cases with significant inflammatory changes. In cases with cirrhosis, the dye had delayed secretion from the hepatocytes.

TABLE OF CONTENTS

S. NO.	TOPIC	PAGES
I	INTRODUCTION	1-7
II	AIMS AND OBJECTIVES	8
III	REVIEW OF LITERATURE	9-21
IV	MATERIALS AND METHODS	22-23
V	OBSERVATIONS AND RESULTS	24-42
VI	DISCUSSION	43-47
VII	SUMMARY AND CONCLUSIONS	48-49
VIII	BIBLIOGRAPHY	50-54
	APPENDICES – I - PROFORMA - MASTER CHART	
	APPENDICES – II - APPROVAL LETTER OF THESIS PLAN - THESIS PLAN	

LIST OF TABLES

Table No.	Title	Page No.
1.	Age Distribution	24
2.	Gender Distribution	25
3.	Comorbid Conditions	26
4.	Previous history of Iodine allergy	27
5.	Associated history of pancreatitis	27
6.	Presenting Symptoms	28
7.	Per Abdomen Examination Findings	29
8.	TLC	30
9.	Bilirubin levels	30
10.	Cases in which USG used	30
11.	Cases in which MRCP used	31
12.	Pre-operative Imaging Findings	31
13.	Duration of surgery	32
14.	Duration of Hospital stay	33
15.	Cases in which ICG used	34
16.	Timing of administration of ICG	34
17.	Adverse reaction to ICG	35
18.	Time to GB visualization	36
19.	Time to Cystic duct visualization	37
20.	Time to CBD visualization	38
21.	Incidence of CBD injury	41
22.	Class of CBD injury	41
23.	Conversion to open surgery	42

LIST OF FIGURES

Fig. No.	Title	Page No.
1.	Variations in cystic duct anatomy and their union with the common bile duct	2
2.	Strasberg classification of CBD injuries	3
3.	Indications of selective IOC	4
4.	Transcystic IOC	5
5(a).	Normal Biliary ductal anatomy	6
5(b).	Parallel union of cystic and common bile duct	7
5(c).	Right Posterior hepatic duct draining into common hepatic duct	7
6.	Flaring of the cystic duct-CBD junction. As a result, the CBD is mistakenly identified as the cystic duct	10
7.	Infundibular view error trap. Dangerous anatomic variants of right posterior hepatic duct draining into the following: A, cystic duct; B, gall bladder neck; and C, common hepatic duct	10
8	Triangle of Safety during Laparoscopic Cholecystectomy	11
9	Stewart way classification of CBD injury	12
10	Strasberg classification of CBD injury	13
11	Anatomy of ducts as seen during ICG cholanangiography	14
12	Bailout procedures in case of difficult cholecystectomies	18
13	Age Distribution	24
14	Gender Distribution	25
15	Comorbid Conditions	26
16	Comorbid conditions and pancreatitis	27
17	Presenting Symptoms	28

18	Per Abdomen Examination Findings	29
19	Pre-operative Imaging Findings	31
20	Duration of surgery	32
21	Duration of Hospital stay	33
22	Timing of administration of ICG	34
23	Adverse reaction to ICG	35
24	Time to first visualization of gall bladder	36
25	Time to first visualization of cystic duct	37
26	Time to first visualization of CBD	38
27	Class of CBD injury	41
28	Conversion to open surgery	42

LIST OF PICTURES

Pic No.	Title
1.	Short Cystic Duct
2.	Parallel Union Of Cd With Cbd
3.	Dilated Cbd
4.	Low Medial Insertion Of Cd
5.	Cbd Stones Identified In Ioc
6.	Normal Biliary Anatomy As Visualized After Calot's Dissection On Real Time Imaging And Nir-Icg Intra-Operative Cholangiography
7.	Short Cystic Duct
8.	Dense Adhesions Around Calot's Triangle As Seen On Real Time And Nir Imaging
9.	Dense Adhesions Around The Calot; S With A Long Cystic Duct
10.	Almost Parallel Union Of The Cd With Cbd. Visualization Of Cd, Chd And Cbd.
11.	Visualization Of The Cd, Chd And Cbd
12.	Due To Dense Adhesions, Partial Visualization Of The Ductal Anatomy
13.	Almost Parallel Union Of The Cd With Cbd. Due To Dense Adhesions, Partial Visualization Of The Cbd
14.	Dilated Cbd
15.	Dense Adhesions Around Cd And Cbd
16.	Dilated Cbd With Dense Adhesions Around Calot's With Non-Visualization Of Cd
17.	Low Medial Insertion Of Cd Into Cbd. Visualization Of Cd, Cbd And Chd
18.	Visualization Od Cd, Cbd And Chd
19.	Artery Bifurcationg Over Anterior Wall. Sludge Present In Cbd. Cbd Stones/Sludge Present
20.	Low Medial Insertion Of Cd

21.	Cbd Stones Present
22.	In View Of Dense Adhesions And Inflammatory Changes, Biliary System Was Not Visualized On Icg-Ioc
23.	In View Of Inflammatory Changes And Cirrhotic Liver, Ductal Anatomy Not Identified On Icg-Ioc
24.	Acute Gangrenous Cholecystitis
25.	Empyema Gb

INTRODUCTION

The first laparoscopic cholecystectomy (LC) was performed in India by Dr. T.E. Udwadia, at JJ Hospital, Mumbai in 1990 and it is one of the most common operations in the surgical field, with more than 60,000 operations performed in Japan and approximately 750,000 in the United States every year.[1,2]

Described for the first time in 1983, the most common indication for laparoscopic cholecystectomy is symptomatic gall stone disease. Indications listed by Society of American Gastrointestinal and Endoscopic Surgeons [SAGES] for laparoscopic cholecystectomy include symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and biliary pancreatitis.[3] Other indications include gall bladder mass/polyp. LC significantly reduced the operating time and post-operative pain as compared to open surgical cholecystectomy. It also has the added advantage of shorter duration of hospital stay and lesser time taken to return to work.

In its initial stages, laparoscopic cholecystectomy was used only for chronic cholecystitis, and then it began to be used for cases like empyema gall bladder, cholecystitis in a patient with a frozen calot's triangle, a history of previous abdominal surgery or in a patient with Mirizzi syndrome, which were considered to be difficult Cholecystectomies.[4,5,6]

The gallbladder is situated on the inferior aspect of the liver, more specifically under the junction of liver segments 4b and 5. The gall bladder can be up to 10 cm in length and physiologically can hold up to 50 cc of fluid (bile). A line from the gallbladder to the inferior vena cava separates the liver into right and left lobes. There are four anatomical sections to the gallbladder: fundus, body, infundibulum, and neck. There is great variation in the biliary ductal anatomy.

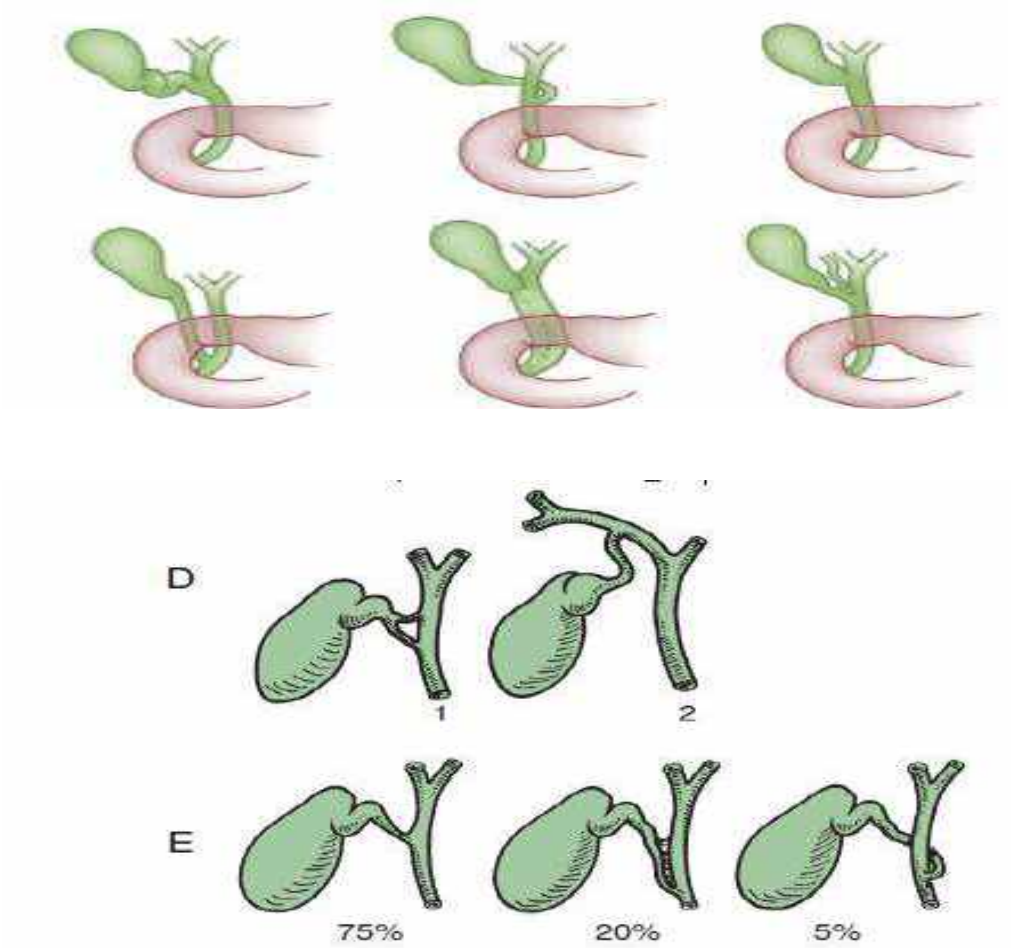


Figure 1: **Variations in cystic duct anatomy and their union with the common bile duct**.

The most dreaded complication during a cholecystectomy still remains to be injury to the common bile duct, the incidence of which varies from 0.1-0.2% in open cholecystectomies and has a still higher incidence of about 0.3 % during LC as mentioned in "Blumgart's Surgery of the Liver, Biliary tract and Pancreas" or even higher of about 0.4-0.6% during LC as per review of several studies on the procedure of LC in various institutes.[7,8] When laparoscopic cholecystectomy was initially introduced, bile duct injury was four times more frequent than for open cholecystectomy and the present estimate is that the incidence remains twice as frequent with laparoscopic versus open cholecystectomy.[9]

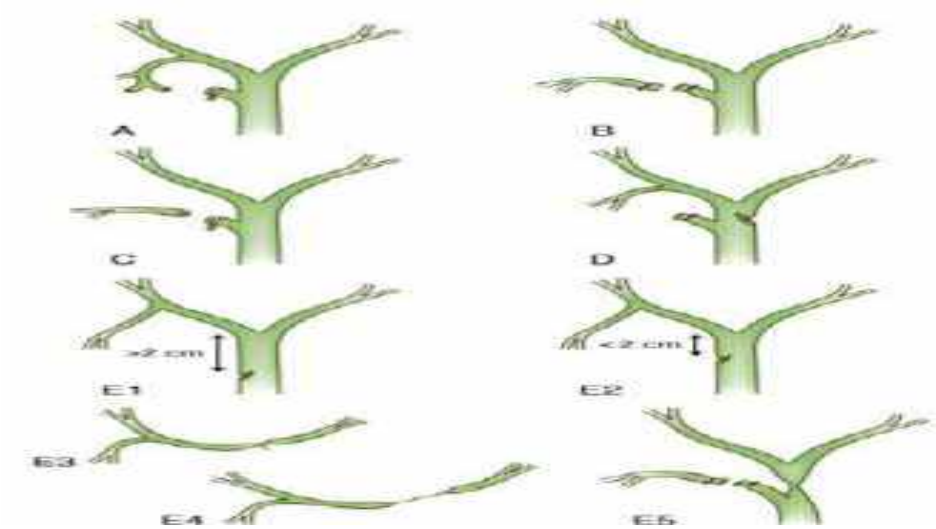


Figure 2: Strasberg classification of CBD injuries

It has been demonstrated that the primary cause of BDI is the misinterpretation of biliary anatomy (71%–97% of all cases)[10,11]

To work around this and to reduce the incidence of injury to the common bile duct during the procedure, intra-operative visualization of the biliary tree was introduced using a cholangiogram. Intra-operative cholangiography using either fluoroscopy or near infrared imaging (NIR) is a technique that is used to visualize the biliary tree by instillation of a contrast agent. This imaging method can be used either routinely as recommended by the SAGES guidelines or selectively based on pre or peri-operative indications.[12]

Indications for the selective use of cholangiography include pain on the day of operation, abnormal hepatic function panel, anomalous or confusing biliary anatomy, and alteration in anatomy that precludes the ability to perform ERCP after cholecystectomy, such as Roux-en-Y gastric bypass, dilated biliary tree, or any preoperative suspicion of choledocholithiasis.

Table 22.1. Indications of selective intraoperative cholangiography

Preoperative indications	History	• Acholic stools • Icterus • Pancreatitis • Cholangitis
	Ultrasound	• Dilated common bile duct
	Biochemical	• Elevated bilirubin • Elevated alkaline phosphatase
	Anatomy which precludes ERCP	• Previous surgery—RYGB • Duodenal diverticulum
Intraoperative indications	• Dilated bile duct • Stones or sludge in cystic or bile duct • Unclear anatomy • Suspected bile duct injury	• Cystic duct >5 mm • Common duct >10 mm

Figure 3: Indications of selective IOC

Intra operative cholangiography (IOC) during LC is not only valuable in detecting common bile duct stones, but also in delineating the anatomy of the biliary ducts, in facilitating dissection, avoiding injuries to the biliary tract and in identifying other abnormalities, such as fistulae, cysts and tumors of the biliary system. Conventional radiographic IOC in a laparoscopic setting is time-consuming, and insertion of a transcystic tube for contrast-material injection may in itself cause bile duct injury. Furthermore, conventional IOC exposes the patient and medical staff to radiation and usually requires a large fluoroscopy machine and additional human resources.

Intra-operative Cholangiography is most commonly used during elective procedures to assess choledocholithiasis but can also be used in cases of biliary tract tumors and hepatic resection. Clinically silent choledocholithiasis occurs in about 1 in 25 cases of biliary colic. This method of intra-op cholangiography has a false positive rate of about 4%. Ideally, IOC should be performed prior to cutting the cystic duct. [13]

Intraoperative fluorescent imaging with indocyanine green (ICG) has been employed for confirming the patency of vascular reconstruction surgery, liver transplantation, anastomosis of the gastrointestinal tract,

brain aneurysms, identification of sentinel lymph node and hepatocellular carcinoma detection.[2]

The methods of using ICG for intra-operative cholangiography include either the transcystic approach wherein the dye is directly injected into the biliary tree via the cystic duct, or any other part of the biliary tree or via an intra-venous infusion, a few minutes to several hours prior to surgery.[14]

The on table approach with direct injection into the biliary tree is done by applying a clip at the junction of the cystic duct with the gall bladder after milking any stone out of the cystic duct into the gall bladder, so as to prevent slippage of stone into the CBD. Then, an anterolateral ductotomy is performed, through which a 4 or 5 Fr cholangiocatheter is inserted into the cystic duct, grasped using an Olsen cholangiogram clamp and after checking patency of the catheter by pushing in Normal saline, about 10 to 20 ml of water soluble contrast in injected into the biliary tree.[15]

Figure 4: Transcystic IOC

The shortcomings associated with IOC may include increased ductal complications like stricture formation and pancreatitis and increased procedure time in inexperienced hands. Critics to this on table procedure also claim that this procedure be used only in cases where the critical view of safety is not achieved.

For intra operative purposes, NIR light (700-900 nm) is more advantageous than visible light due to its capability to penetrate deeper into tissue, up to 10 mm. In addition, in the NIR spectrum tissue exhibits almost no auto fluorescence. NIR fluorescent contrast agents lead therefore to maximized signal-to-background ratios and enhance the contrast of different tissue types.[16]

ICG is a water soluble tricarbocyanine molecule that is almost completely protein bound following intravenous injection. Following intravenous injection, it rapidly and completely binds to albumin and is selectively taken up by hepatocytes, metabolized and excreted in bile. The angiographic feature of ICG is based on its fluorescent character in the near-infrared range between 790 and 805 nm, which can be detected by specialized infrared video cameras. The fact that ICG is metabolized in the liver and excreted via bile makes it an excellent medium for biliary tree imaging.[17]

Indocyanine green has been developed as a new method for performing intra-operative cholangiography. This helps to delineate difficult anatomy of the biliary tract, identify choledocholithiasis or guide biliary reconstruction.

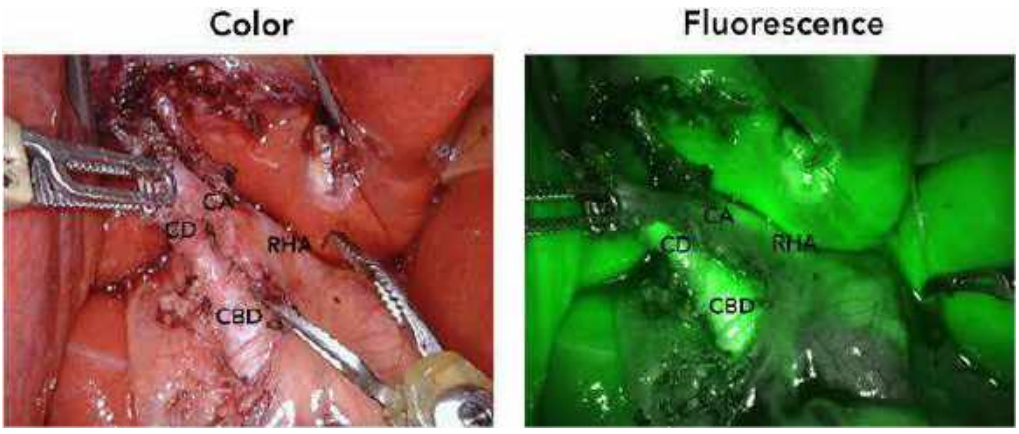


Figure 5a:- Normal Biliary ductal anatomy

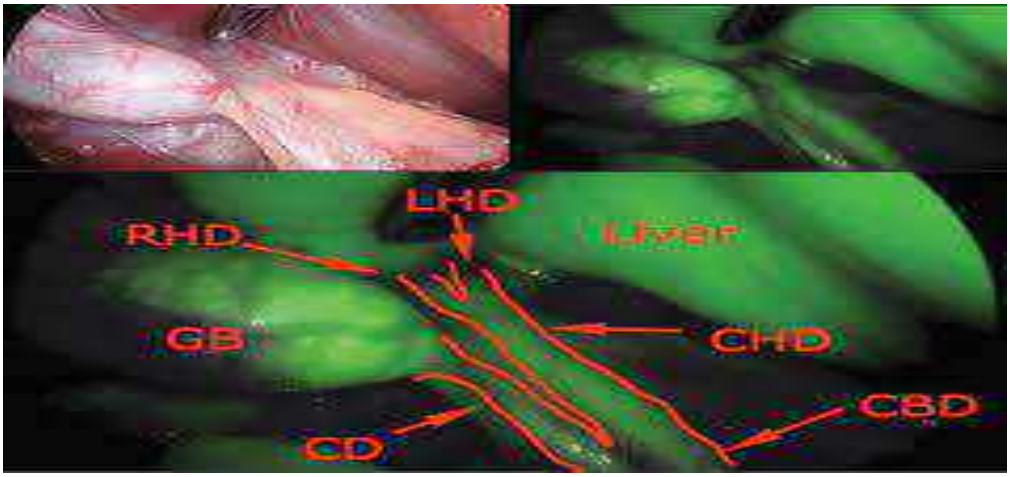


Figure 5b:- Parallel union of cystic and common bile duct

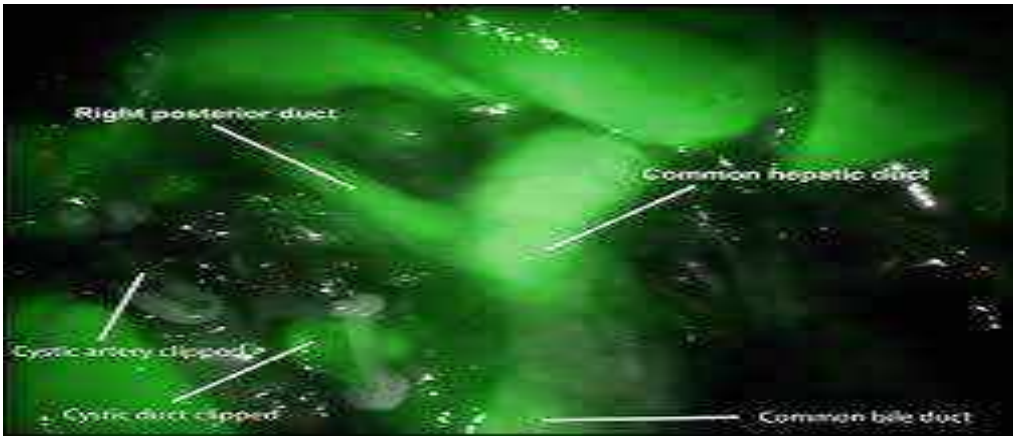


Figure 5c:- Right Posterior hepatic duct draining into common hepatic duct

Conversion to open surgery is considered a complication by some whereas a mature judgement by others. Primary reasons to consider a conversion include unclear anatomy, intraoperative complications, failure to progress in a timely manner, and pathology, including choledocholithiasis not amenable to laparoscopic or postoperative endoscopic techniques. The complications that may require conversion to open surgery include massive hemorrhage, bowel perforation or injury to the bile duct. The rate of conversion to open surgery is around 5-10 %.[18]

The surgery has a rate of conversion to open of about 2-5% when used without indocyanine green, which is increased to 10-15 % in cases of emergency cholecystectomy for acute cholecystitis.[19]

Aims and Objectives

1. Feasibility and safety of using ICG in lap. Cholecystectomy.
2. Post-operative outcome in patients undergoing lap. Cholecystectomy with ICG.
3. Timing of ICG administration for near infrared imaging in lap. Cholecystectomy.

Review of Literature

Laparoscopic Cholecystectomy is one of the most commonly performed laparoscopic procedures worldwide and though may seem like an easy procedure, has a number of serious complications. One of which is injury to the common bile duct due to misidentification of the duct. Misperception by the surgeon of what he or she is seeing in the operative field is a major factor in generating bile duct injury.[14,17] Prevention of such injuries by careful dissection, accurate knowledge of anatomy and appropriate precautionary measures is very important.

The key principles for safe laparoscopic cholecystectomy include the following:[9]

1. 30-degree or 45-degree high-definition laparoscope.
2. Cephalad traction on the dome of the gallbladder and Lateral traction on the infundibulum
3. Finding the gallbladder wall and staying on it
4. Dissecting from above down to the neck
5. Widely opening the hepatocystic triangle
6. Moving the infundibulum back and forth (wave the flag) repeatedly looking at both sides of the gallbladder
7. Critical view of safety
8. Dividing the cystic duct as close to the gallbladder as possible
9. Never dividing the cystic duct with any cauterizing instrument as if it turns out to be the common bile duct, the resulting ischemic injury will only lessen the chances for a good repair.

Most of these injuries are not identified at the time of surgery. If detected at operation or within 48 hours of surgery, the surgeon should proceed with repair of these injuries.[7] A study conducted in 2015 on laparoscopic cholecystectomies performed for acute cholecystitis, showed 30-49% surgeons performing cholecystectomies will have a bile duct injury in their career.[9]

Strasberg and colleagues define an error trap as an operative approach that works well in most circumstances but fails to do so in certain circumstances.

The error traps that Strasberg and colleagues described are as follows:

1. The ‘‘infundibular view’’ error trap

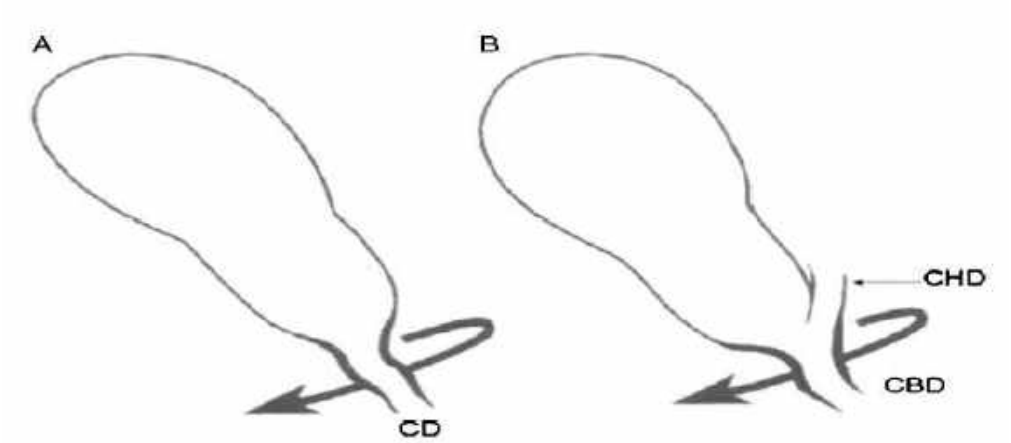


Figure6: Flaring of the cystic duct-CBD junction. As a result, the CBD is mistakenly identified as the cystic duct.

2. Fundus down cholecystectomy in the face of severe Inflammation.
3. Failure to perceive the presence of an aberrant right hepatic duct on cholangiography (IOC). Failure to recognize an aberrant right hepatic duct or posterior right hepatic duct intraoperatively as well.

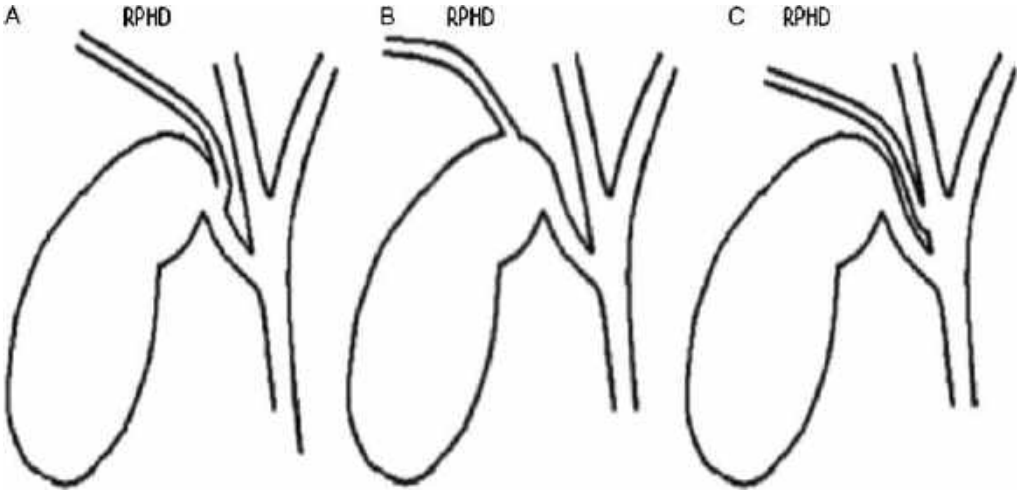


Figure7: Infundibular view error trap. Dangerous anatomic variants of right posterior hepatic duct draining into the following: A, cystic duct; B, gall bladder neck; and C, common hepatic duct.

4. Injury to the common bile duct in the case of a ‘‘parallel union’’ cystic duct.[9,20-25]

Strasberg states that the worst injuries occur in those patients who undergo conversion from laparoscopic to open cholecystectomy, performed top-down because of marked inflammation and difficult dissection. The perceived, safe operative plane coming down the medial wall of the gallbladder is in such cases obliterated by an inflammatory reaction, which incorporates the right-sided porta hepatis and the common bile duct. Thus, this injury is commonly associated with major biliary and vascular injury, at times requiring liver resection for the ischemic injury.

In a study by Stewart and law, only 17 % of injuries repaired by the primary surgeon, were successful. Considering this, in case an injury has occurred, only an experienced surgeon should proceed with repair of these injuries.[26]

Appropriate steps to prevent injury, include careful dissection around the calot’s triangle, following the critical view of safety technique introduced by Strasberg in 1995.[28,31] The SAGES expert Delphi consensus has deemed the critical view of safety to be the most critical factor for overall safety during laparoscopic cholecystectomy.

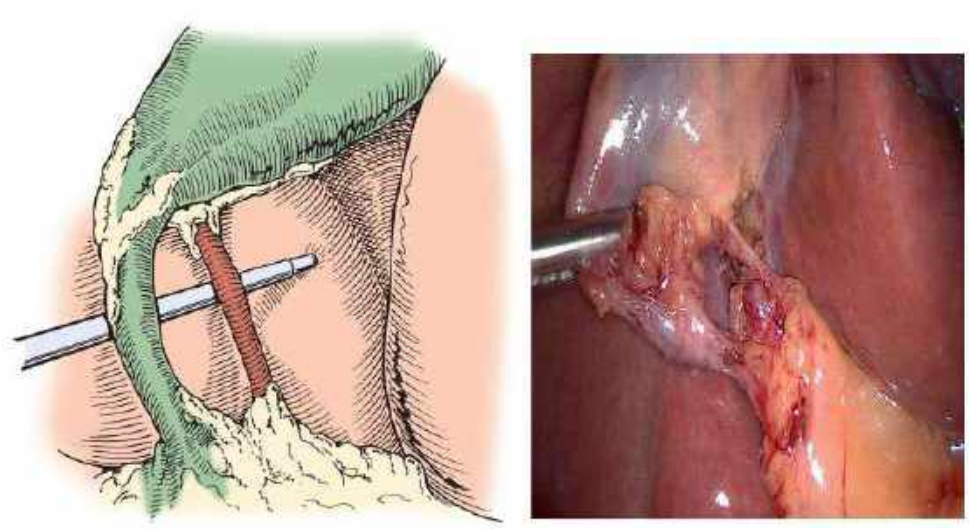


Figure8: Triangle of Safety during Laparoscopic Cholecystectomy

Various classifications have been provided for CBD injuries during laparoscopic cholecystectomy, based on their relations to the cystic duct and vascular lesions around.

One such used classification is the Stewart-Way classification:

- Class I injuries involve an incision (i.e., an incomplete transaction) of the CBD and typically occur when the CBD is mistaken for a cystic duct.
- Class II injuries represent lateral damage to the common hepatic duct.
- Class III injuries are the most common and represent a CBD mistaken for a cystic duct; these are not immediately recognized intraoperatively.
- Finally, class IV injuries occur when a right hepatic duct is mistaken for a cystic duct.[13,28]

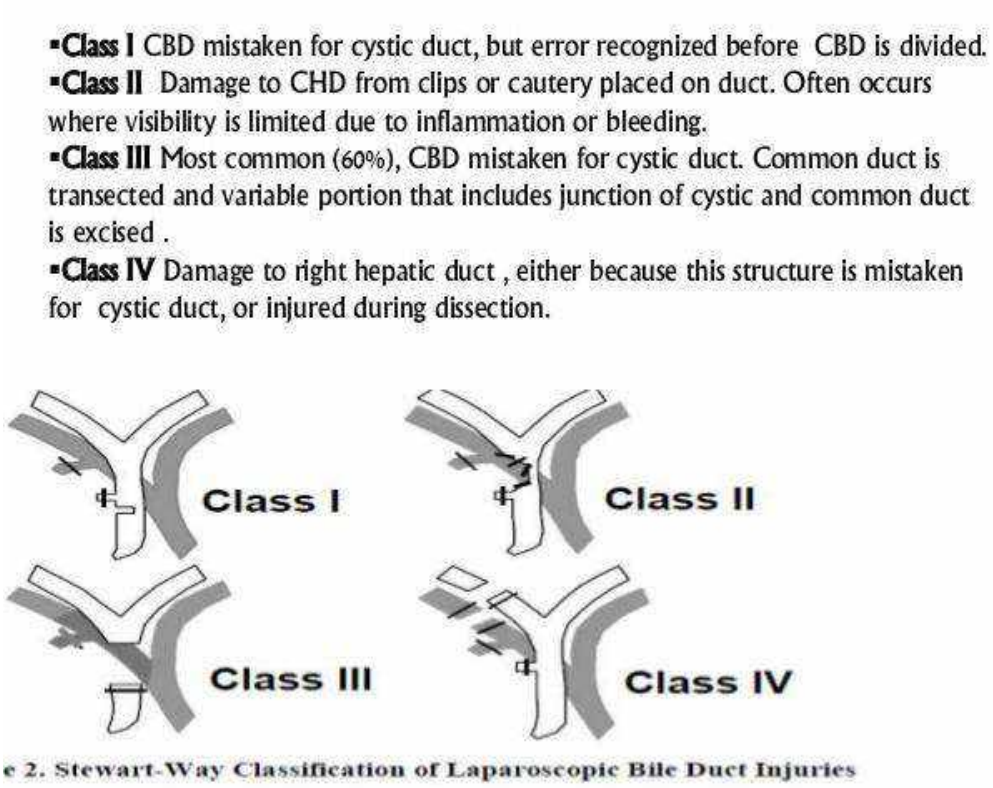

▪Class I CBD mistaken for cystic duct, but error recognized before CBD is divided.
▪Class II Damage to CHD from clips or cautery placed on duct. Often occurs where visibility is limited due to inflammation or bleeding.
▪Class III Most common (60%), CBD mistaken for cystic duct. Common duct is transected and variable portion that includes junction of cystic and common duct is excised .
▪Class IV Damage to right hepatic duct , either because this structure is mistaken for cystic duct, or injured during dissection.
Class I
Class II
Class III
Class IV
e 2. Stewart-Way Classification of Laparoscopic Bile Duct Injuries

Figure 9: Stewart way classification of CBD injury

If cannulation of the CBD, rather than the cystic duct, occurs, during intra-operative cholangiography, the cholangiocatheter can be removed, and the ductotomy can be addressed by primary repair or by placing a T-tube, without the need for a formal biliary reconstruction. A

T-tube for large defects would allow the CBD to heal without stricture formation, and the tube can be removed non operatively several weeks after the cholecystectomy following cholangiography. The alternative scenario is complete transection of the CBD, a class III injury. In the absence of cholangiography, this transection is seldom recognized intra operatively, typically presents postoperatively, and results in significant patient morbidity. Management requires an open bilioenteric anastomosis for repair; thus IOC has the potential to not only prevent bile duct injury, but also to mitigate its impact if injury does occur.[13]

The Strasberg classification for CBD injuries goes as follows:

- Type A - Bile leak from a minor duct retaining continuity with the common bile duct.
- Types B and C - Creation of discontinuity for part of the biliary tree. Ductal occlusion injuries are designated as type B and transections without occlusion as type C.
- Type D - Lateral injury to the major bile duct. These injuries are partial (i.e.50%).
- Type E - Circumferential injury to the major bile duct. These injuries are further divided into five types (E1 to E5). Types E1 to E4 are based on the level of injury, whereas E5 is a combination of common hepatic and right sectoral duct injury

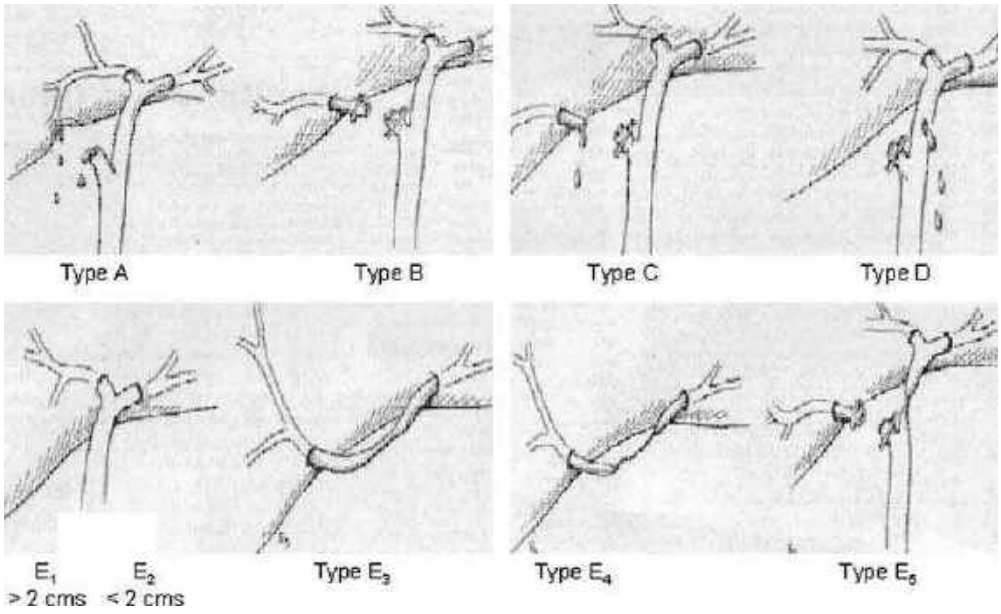


Figure 10: Strasberg classification of CBD injury

Studies suggest that near infrared imaging with ICG provides a good overall visualization of the cystic, common bile, common hepatic ducts and the cystic duct junction with CBD prior to and following the dissection of Calot's triangle as proven by Vlek et al in their study in 2016. [29]

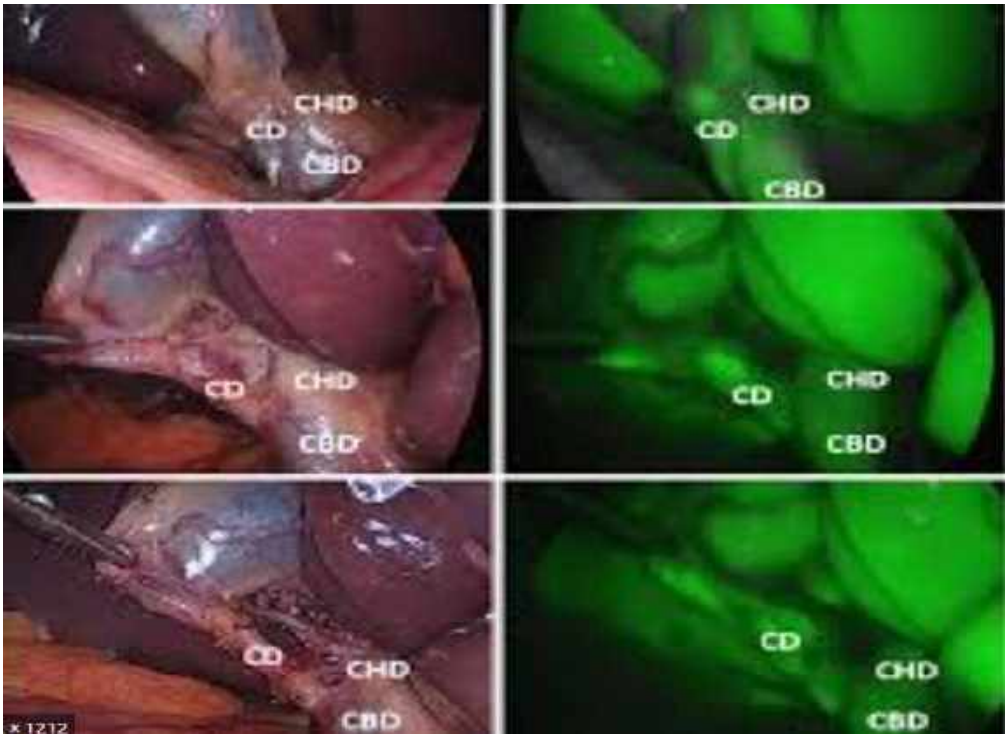


Figure11: Anatomy of ducts as seen during ICG cholanangiography

Fluorescence Imaging is one of the most popular imaging modes in biomedical sciences for the visualisation of cells and tissues both in vitro and in vivo. The benefits of FI include:

(i) High contrast, that is, signal to noise ratio (SNR): only the target, not background, is visible because separate wavelengths are used for illumination and recording

(ii) High sensitivity: extremely small concentrations can often be made visible;

(iii) Gives molecular information: makes some (bio) chemistry spatially and temporally visible;

(iv) Great tools for research: several possible imaging modes, most of which are unique;

(v) Cheap: the optical instrumentation and computing needed are quite simple;

(vi) Easy to use: resembles classical staining[30]

NIR fluorescence imaging requires a NIR fluorescent agent (ie, fluorophore) combined with an imaging system that is able to both excite and detect the fluorophore. The fluorescence signal can be visualized after milliseconds, which is advantageous above other emerging imaging techniques, such as Raman spectroscopy or Optical Coherence Tomography, which require more time to visualize the same field of view.[28] Moreover, most systems are capable of merging fluorescence signals with normal RGB color videos, allowing direct anatomical orientation.[14]

Indocyanine green acts as an imaging agent, which is sterile, water soluble, and has a peak spectral absorption averaging at 805nm in blood.

It does not undergo enterohepatic recirculation. It only stays in the blood for about 8 minutes after injection. The removal of ICG depends on several factors, including the blood flow of the liver, biliary excretion, and parenchymal cellular function.[31]

ICG has several clinically excellent properties, which has been thoroughly verified during its long clinical use:

(i) Patient safety: nontoxic and non-ionizing,

(ii) Ideal for angiography: binds efficiently to blood lipoproteins, that is, it does not leak from circulation,

(iii) Short life time in blood circulation allowing repeated applications,

(iv) Good SNR: there is not much NIR auto fluorescence in tissue giving low noise background,

(v) Deep imaging: operates in tissue optical window (NIR), and

(vi) Simple and cheap imaging devices

Fluorescent IOC with intravenous ICG injection has potential advantages over radiographic IOC. First, the technique we described can save time and avoid bile duct injury associated with the insertion of a transcystic tube.[2] Second, it is convenient. Using only a preoperative intravenous ICG injection, surgeons can obtain fluorescent images of

the biliary tract at any time, without radiation technicians. Third, fluorescent imaging enables the distinct identification of the biliary tract in relation to surrounding structures and organs, though its ability to detect common bile duct stones remains unclear. Lastly, fluorescent IOC is safe. It does not require irradiation, and the risk related to the administration of ICG is quite small (approximately 0.003% at doses in excess of 0.5 mg/kg)[14]

During IOC, the fluoroscopic images should be assessed for length of the cystic duct and its junction with the CBD, diameter of the CBD, any luminal filling defects within the CBD, free flow of contrast into the duodenum and anatomy of the intrahepatic biliary tree.[18]

This visualization requires pre-operative injection with ICG in order for it to accumulate in the biliary system. The standard dose for this can vary depending upon the time interval between injection and surgery. In their study vlek et al, used either a 2.5 mg standard dose or of 0.05mg/kg dosage administered anywhere between one hour prior to anaesthesia to just after administration of anaesthesia.[29]

Sometimes, fluorescence may not be detected 45 minutes after the injection of ICG. Therefore, when this happens, the second dose of 2.5 µg of ICG can be administered. Also a second injection of ICG can be given if there is anything regarding vascularity that cannot be clearly understood during the surgery. Apart from its role to analyze the extra hepatic biliary anatomy better, thus reducing the incidence of bile duct injury, it also plays a role in identifying the anatomic structure in a quick manner, thereby reducing the time used in performing the procedure of cholangiography and hence also shortening the entire duration of surgery.[31]

Zarrinpar et al in 2016 reported on the dose and timings of ICG administration for intra-operative cholangiography and concluded that a dose of 0.25 mg/kg administered at least 45 minutes prior to surgery facilitates intraoperative anatomical identification.[32]

Boni et al. reported 100 % sensitivity of ICG fluorescence in identifying the cystic and common bile ducts during 52 laparoscopic cholecystectomies.[33,34]

In their study in 2015, Dieuwertje et al found no significant difference between conventional laparoscopic cholecystectomy and cholecystectomy using near infrared imaging at critical view of safety but with ICG , cystic duct was identified significantly earlier with the NIR camera, where they used ICG injection at a dose of 0.05 mg/kg administered 1-2 hours prior to surgery.[35]

Gangemi et al reported in their study that the use of ICG during laparoscopic cholecystectomy was associated with a significant reduction in the rate of conversion from laparoscopic to open cholecystectomy.[36]

In a study by tsutsui et al, wherein they assessed intra-operative cholangiography with ICG by means of luminance intensity ratios between various structures of the hepatobiliary system and also the visibility of the gall bladder, cystic duct and CBD. They found the proportion of cases in which two or more evaluators classified the visibility of the gallbladder and bile duct as grade A first increased in the 12 hour study group, reached a peak in the 15 hour group and then decreased from then on and thus concluded that the best timing for administration of ICG is 15 hours prior to surgery when given at a standard dose of 25 mg. [37]

In a large meta-analysis by Ludwig et al, of more than 300,000 laparoscopic cholecystectomies, which included 405 major bile duct injuries, the incidence of major bile duct injury was 0.21% in the group where routine cholangiography was used as compared with 0.43% in the selective cholangiography group, representing a statistically significant reduction. Furthermore, 87% of the injuries were diagnosed at the time of surgery in the routine group, compared with only 45% in the selective group.[38]

In a study conducted by Turcotte et al in 2020, on usage of ICG for cholecystectomies on exclusively emergency cases, showed only a 0.5 % decrease in bile duct injury.[39] This study showed that the total hospital stay in the ICG group was shorter, but no differences in rates of infection, bile leak or 30 day return to hospital were seen. It also

suggested that in cases of acute cholecystitis with cystic duct obstruction, ICG cholangiography was less successful.

A bailout operation is described as a laparoscopic partial or subtotal cholecystectomy or a case converted to open in order to avoid bile duct injuries

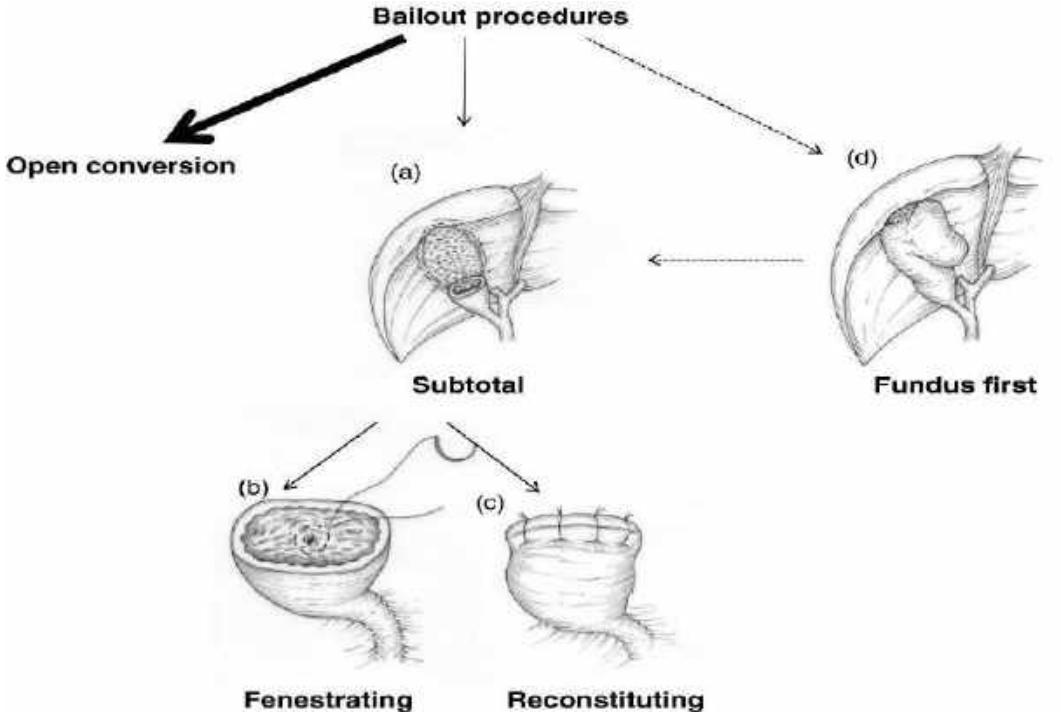


Figure12: Bailout procedures in case of difficult cholecystectomies

In a large multicentre clinical trial by Dip et al in 2019, on comparison of white light imaging versus near infrared light imaging for visualization of biliary structures, found a statistically significant difference in the visualization of all 7 structures (cystic duct, cystic duct – gall bladder junction, common bile duct, cystic-common bile duct junction, right hepatic duct, common hepatic duct and accessory ducts), averaging roughly 3 fold enhanced visualization in the NIFC arm compared to the only WLI arm.[40]

Recently, a large, randomized controlled trial evaluating the rate of anatomic identification during laparoscopic cholecystectomy with ICG versus traditional white light laparoscopy demonstrated improved visualization of specific structures using ICG cholangiography as

measured by postoperative surgeon survey. When evaluating factors determining visualization, the authors found that overall visualization was decreased in patients as the severity of inflammation increased, but patients with severe inflammation were a minority of patients in this study, and patients with cholecystitis were not evaluated separately.[40]

In a study by Kim KH, across 66 patients who underwent laparoscopic cholecystectomy with ICG fluorescence intra-operative cholangiography, they were not able to visualize the extrahepatic biliary system in 5 patients, who had undergone previous ERCP.[41]

In a prospective study by A. Arun et al in 2020, 199 patients were injected with ICG 30 minutes prior to surgery, including both simple (symptomatic gall stone disease) and difficult (acute or chronic cholecystitis, biliary pancreatitis, perforated gall bladder, empyema) cholecystectomies. They showed that extrahepatic structures were identified even in more than 75 % of difficult cases excluding gangrenous gall bladder.

They also concluded that, with rising severity of inflammation the visualization of extra-hepatic biliary structures using ICG dye with NIRC is getting obscured.[33,42]

Keeratibharat N. et al performed lap. Cholecystectomy in 20 patients with fluorescence IOC and concluded that intra-operative fluorescent cholangiography appears to be a safe and efficient approach for extra-hepatic anatomy identification during laparoscopic cholecystectomy. They were able to visualize the cystic duct and the confluence in 18 of 20 patients prior to dissection of the calot's triangle.[43]

Left sided gall bladder is associated with a higher incidence of bile duct injury (4.4%), necessitating the establishment of a safe surgical approach in these patients. Kim KH demonstrated that ICG fluorescence cholangiography should be used in cases of left-sided gallbladder during laparoscopic cholecystectomy. An assessment of the extra- and intrahepatic biliary system is essential to avoid biliary injury in cases of left-sided gallbladder.[44]

Pesce A. et al in 2017 conducted a study on intraoperative cholangiography in 50 patients undergoing laparoscopic

cholecystectomy and concluded that the common hepatic duct (CHD) and the common bile duct (CBD) were identified successfully in 12 of 50 patients (24%) and in 33 of 50 patients (66%) before Calot's dissection respectively and in 26 of 50 patients (52%) and in 47 of 50 patients (94%) after complete Calot's dissection ($p = 0.007$ and $p = 0.001$, respectively). Significant differences were observed for CBD visualization rate, in relation to BMI after Calot's dissection ($p < 0.05$) and history of cholecystitis, before Calot's dissection ($p = 0.017$).[45]

Relative Contraindications to the use of ICG are iodine allergy, pregnancy, liver disease, uremia and aprevious anaphylactic reaction to a dye injection.

Adverse reactions to ICG

Can be classified into mild, moderate and severe.

1. Mild: transient effect that did not require any treatment.
2. Moderate: transient effect that may or may not require medical treatment.
3. Severe: Prolonged effect that requires intense treatment.
4. Death is attributed to the use of intravenous ICG if symptoms start within 24 hours and the event occurrs within 48 hours of the procedure.[46]

Indocyanine green can cause adverse reactions by an allergic or a pseudo-allergic mechanism. Mild and moderate adverse reactions appear to be pseudo-allergic in nature, mediated by a non-immunologic release of histamine, whereas severe adverse reactions may be mediated by a hapten-protein complex mediated IgE activation, resulting in activation of mast cells with a subsequent release of histamine and other kinins. This severe reaction in not known to be dose dependent.[51]

Radiocontrast media is known to disrupt the endothelial lining of blood vessels releasing plasminogen activator, which in turn causes activation of the complement system and ICG may also act in a similar way of causing an allergic reaction.

Prednisolone and Diphenhydramine for premedication has been used in patients receiving other iodine-based contrast media, who were previously known to have been sensitized to iodine (Allergic), but this premedication has not successfully been reciprocated with ICG.

A Study by Benya et al in 1989 reported a case of an adverse reaction in a 63 years old male including nausea, shortness of breath with wheezing and urticaria, immediately after injection of the dye, which was managed with diphenhydramine and methylprednisolone. They also reviewed 16 previous such incidents with similar reactions and one involving death of the patient. They concluded that the dye could cause sensitization as one such case involved serial injection of the dye three times on three separate occasions, with worsening of the symptoms on each occasion.[47]

MATERIALS AND METHODS

Source of Data

The study was conducted among the patients admitted to the department of general surgery, Dayanand Medical College and hospital, Ludhiana.

Method of Collection of Data

Information was collected through a pre-designed proforma for each patient that has been chosen to be a part of the study with detailed history, clinical examination and complete investigational work-up.

Inclusion Criteria

1. Patients undergoing lap. Cholecystectomy for any indication.
2. Patients with pre-operative imaging of the gall bladder using ultrasound or MRCP.

Exclusion Criteria

1. History of previous intervention (cholecystostomy).
2. Patients with co-morbidities that rule out the possibility of laparoscopic surgery.

Methods of Collection

The study was conducted on patients undergoing laparoscopic cholecystectomy with the usage of indocyanine green dye and near-infrared camera imaging for visualization of the hepatobiliary system during LC.

Patient related factors recorded were age, gender, presence or absence of diabetes, acute or chronic duration of the disease, history of pancreatitis, pre-operative ERCP. Patients with jaundice pre-operatively or suspicion of CBD stone were evaluated with MRCP. All efforts were made to eliminate any local skin infection etc. pre-operatively.

The patients were injected pre-operatively with 5 mg of ICG. LC was performed using a standard four port technique, where pneumoperitoneum was created by CO2 insufflation using Veress needle via a Supraumbilical incision, which is then used as the camera port and three working ports then inserted in the right lumbar, right

anterior axillary line and the epigastric regions. The procedure is performed using a "Karl Storz HD image S1 system" with “D-light P”, light source for NIR-ICG intra-operative cholangiography. After adhesiolysis, Calot’s dissection was performed using a combination of blunt and sharp dissection with electrocautery to reach the critical view of safety. After completing calot's dissection, time to first visualization of the cystic duct, gall bladder and CBD were documented periodically in every case. After identification of the duct system using real time imaging and NIR imaging, the cystic duct and artery were clipped using metallic endoclips and divided in between. GB was separated from its bed on liver using electrocautery dissection and after confirming hemostasis, pneumoperitoneum reduced and skin at port sites closed using Ethilon 2-0 or staplers.

Sample Size: Time Bound Study.

Follow-Up Period: Upto discharge from the hospital.

Duration of Study: July 2020 to December 2021

Outcome

To find out the feasibility, safety and outcomes of laparoscopic cholecystectomy performed with usage of indocyanine green dye by means of assessment of operation time, bile duct or vascular injury, infection, need for repeat procedure/intervention.

Statistical Analysis

Data has been described in the terms of range, mean +/- standard deviation, median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables will be done using paired t-test. A probability value of less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS ver. 21.

OBSERVATIONS AND RESULTS

This study was conducted on 71 consenting patients with various gall stone disease who underwent Laparoscopic Cholecystectomy using a 4 port technique. They were followed up during the hospital stay until discharge from the hospital and the following observations were made:

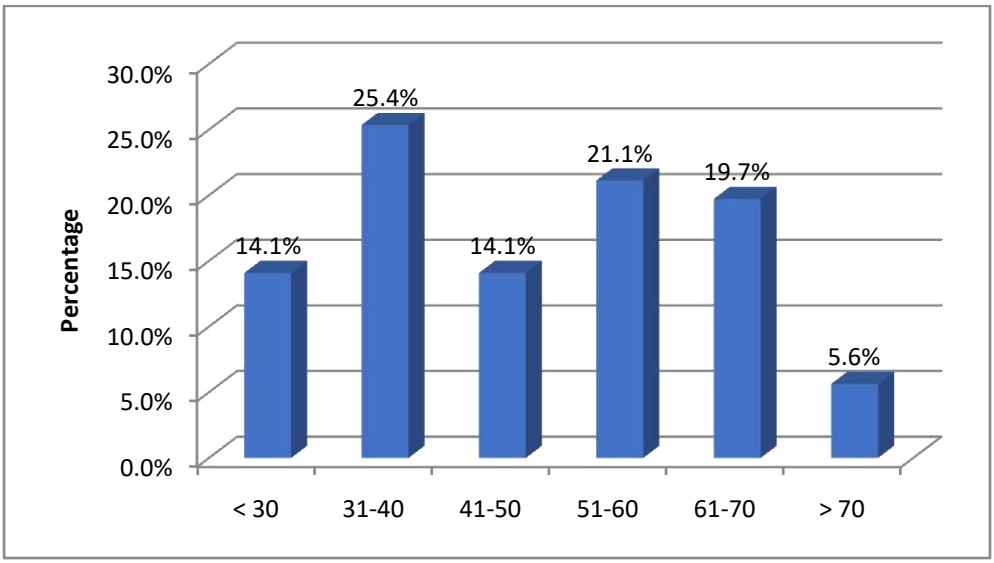
AGE

The age of the patients ranged from 18 to 84 years of age. Mean age was 48.20 years. Most of the patients (57 of 71) were between the 4th and 7th decades of life (80.3 %), while only 4/71 patients were above the 71 years of age (5.6 %).

Table1: Age Distribution

Age	No. of cases	Percentage
< 30	10	14.1%
31-40	18	25.4%
41-50	10	14.1%
51-60	15	21.1%
61-70	14	19.7%
> 70	4	5.6%
Total	71	100.0%

Figure 13: Age Distribution



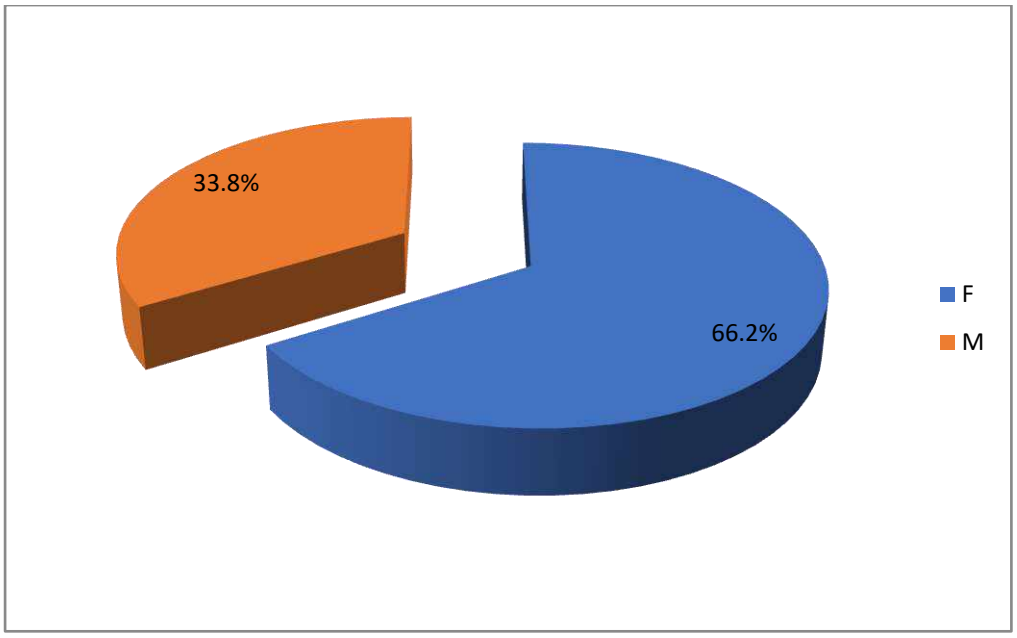
GENDER

In this study, there was predominance of females (66.2%) as compared to males (33.8%).

Table 2: Gender Distribution

Sex	No. of cases	Percentage
Females	47	66.2%
Males	24	33.8%
Total	71	100.0%

Figure 14: Gender distribution



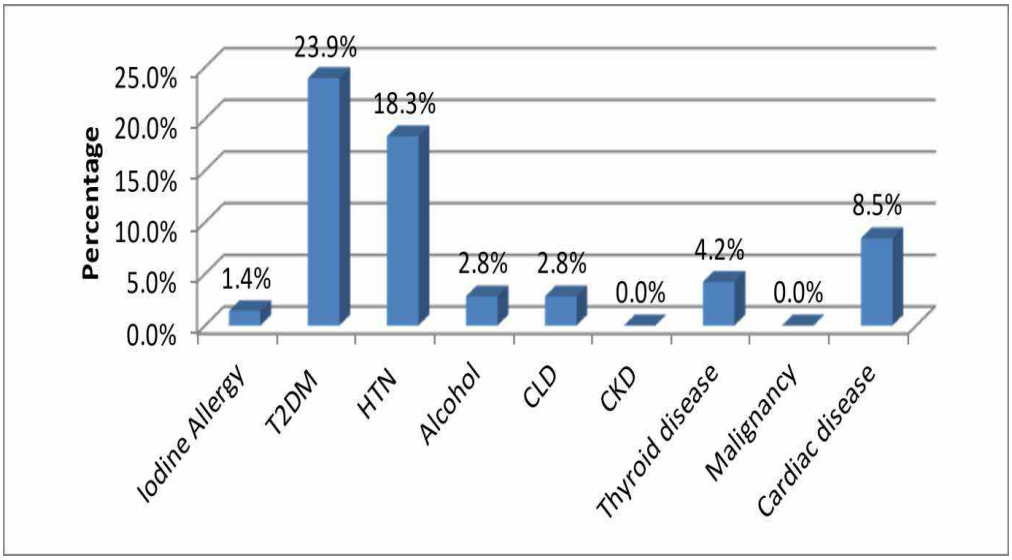
ASSOCIATED COMORBID CONDITIONS

23.9% (17) were patients of Type-II Diabetes Mellitus, 18.3 % (13 patients) of the patients had Hypertension and 8.5 %(6) had a co-existing Cardiac disease.

Table 3: Comorbid Conditions

Type-Ii Diabetes Mellitus	17	23.9%
Hypertension	13	18.3%
Alcohol Consumption	2	2.8%
Chronic Liver Disease	2	2.8%
Thyroid Disease	3	4.2%
Cardiac Disease	6	8.5%
Bladder Outlet Obstruction	1	1.4%
Bronchial Asthma	1	1.4%
Cerebrovascular Accident	1	1.4%
Parkinson's	1	1.4%
Pituitary Macroadenoma	1	1.4%
Rheumatoid Arthritis	1	1.4%
Solitary Kidney,Ptb	1	1.4%

Figure 15: Comorbid Conditions



History of Iodine Allergy

One patient had a previous history of Iodine allergy for which she was not administered with ICG pre-operatively.

Table 4: Previous history of Iodine allergy

Iodine Allergy	1	1.4%

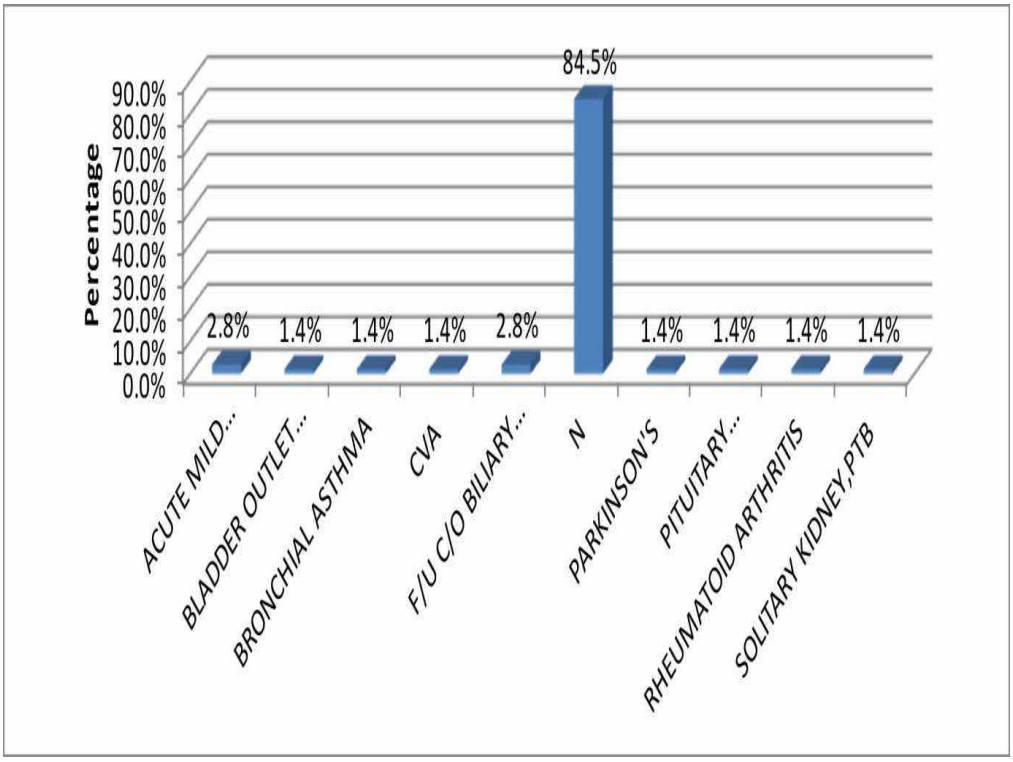
History of Pancreatitis

2(2.8%) patients were operated in the first week of acute mild gall stone induced pancreatitis while 2 patients (2.8%) had previous histories of biliary pancreatitis and were undergoing interval cholecystectomy.

Table 5: Associated history of pancreatitis

F/U C/O Biliary Pancreatitis	2	2.8%
Mild Aciute Pancreatitis	2	2.8%

Figure 16: Comorbid conditions and pancreatitis



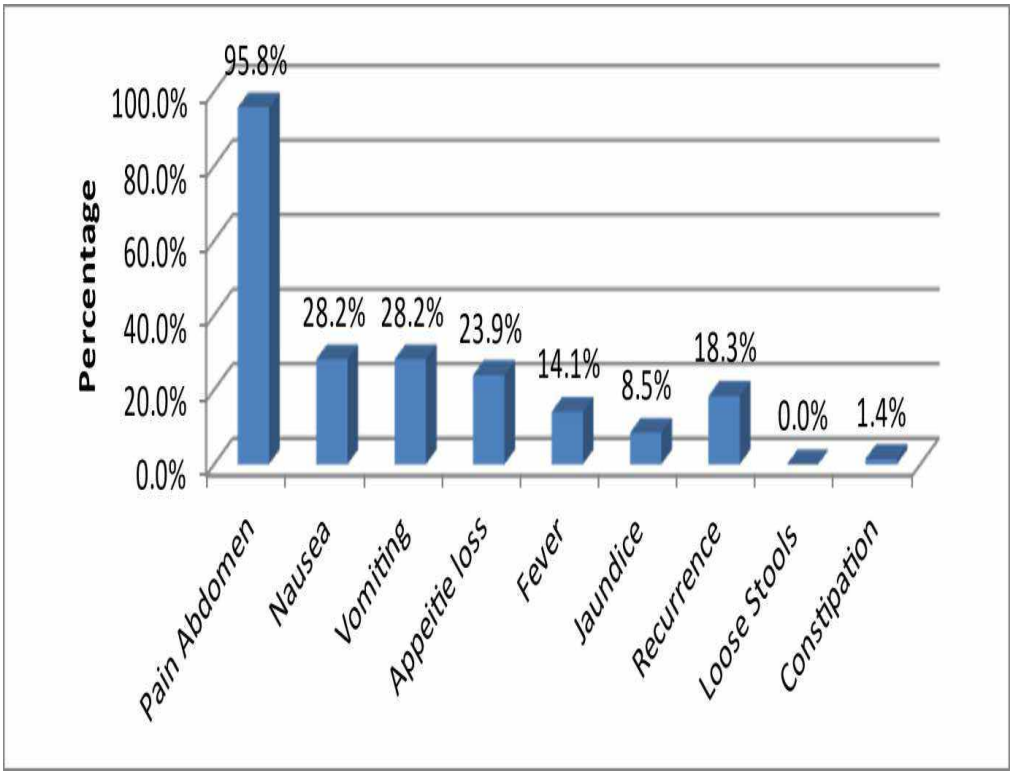
Symptom/S at the Time of Presentation

Majority of the patients presented with pain abdomen (95.8%). While 13 (18.3%) had a history of the recurrence of symptoms of pain abdomen. 6 of the 71 (8.5%) had jaundice at the time of presentation.

Table 6: Presenting Symptoms

Symptoms	No. of cases	Percentage
Pain Abdomen	68	95.8%
Nausea	20	28.2%
Vomiting	20	28.2%
Appeitie loss	17	23.9%
Fever	10	14.1%
Jaundice	6	8.5%
Recurrence	13	18.3%
Constipation	1	1.4%

Figure 17: Presenting Symptoms



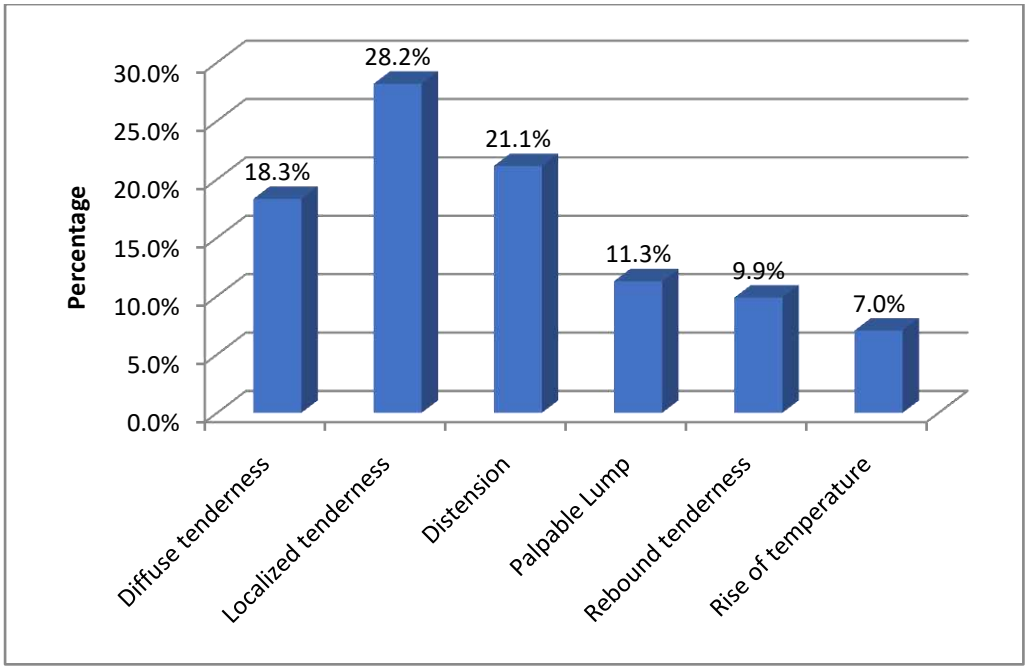
Examination Findings

8 patients (11.3%) had a palpable per abdomen lump, 13 (18.3%) had diffuse abdominal tenderness while 20(28.3%) had localized abdominal tenderness.

Table 7: Per Abdomen Examination Findings

	No. of cases	Percentage
Diffuse tenderness	13	18.3%
Localized tenderness	20	28.2%
Abdominal Distension	15	21.1%
Palpable Lump	8	11.3%
Rebound tenderness	7	9.9%
Rise of temperature	5	7.0%

Figure 18: Per Abdomen Examination Findings



Lab parameters

1. TLC

TLC in the study population varied between 4 and 22000 with a mean of 9000 (9.02 +/- 3.95).

Table 8: TLC

Parameter	Total cases	Minimum Value	Maximum Value	Mean	Range
TLC	71	4.00	22.00	9.02	3.95

2. Total and Direct Bilirubin

The total bilirubin varied between 0.24 and 2.56 with a mean of 0.67 and direct bilirubin varied between 0.05 and 2.21 with a mean on 0.25.

Table 9: Bilirubin levels

Parameter	Total cases	Minimum Value	Maximum Value	Mean	Range
Total Bilirubin	71	0.24	2.56	0.67	0.39
Direct Bilirubin	71	0.05	2.21	0.25	0.28

Pre-operative imaging method used

All the patients had a pre-operative Ultrasound abdomen and 9 patients (12.7%) had a MRCP in view of CBD stones. Most common indication for the surgery was symptomatic gall stone disease, in 34 of 71 patients (47.9%). 23 patients had chronic calculous cholecystitis (32.4%).

Table 10: Cases in which USG used

USG	No. of cases	Percentage
No	2	2.8%
Yes	69	97.2%
Total	71	100.0%

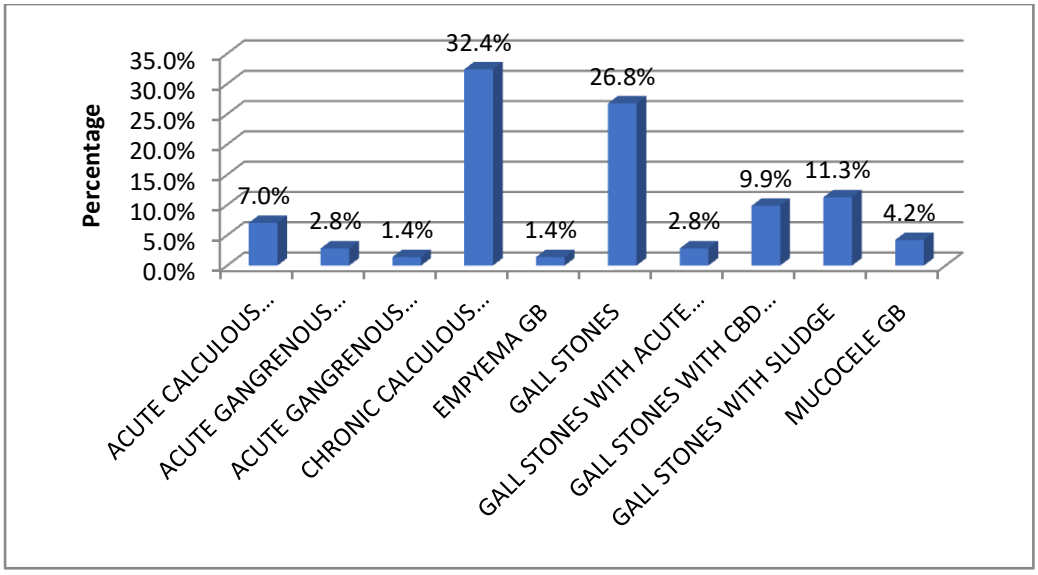
Table 11: Cases in which MRCP used

MRCP	No. of cases	Percentage
No	62	87.3%
Yes	9	12.7%
Total	71	100.0%

Table 12: Pre-operative Imaging Findings

Imaging Findings	No. of cases	Percentage
Acute Calculous Cholecystitis	5	7.0%
Acute Gangrenous Cholecystitis	2	2.8%
Acute Gangrenous Cholecystitis With Intrahepatic Perforation	1	1.4%
Chronic Calculous Cholecystitis	23	32.4%
Empyema Gb	1	1.4%
Gall Stones	19	26.8%
Gall Stones With Acute Pancreatitis With Peripancreatic Fluid	2	2.8%
Gall Stones With Cbd Stones	7	9.9%
Gall Stones With Sludge	8	11.3%
Mucocele Gb	3	4.2%
Total	71	100.0%

Figure 19: Pre-operative imaging finding



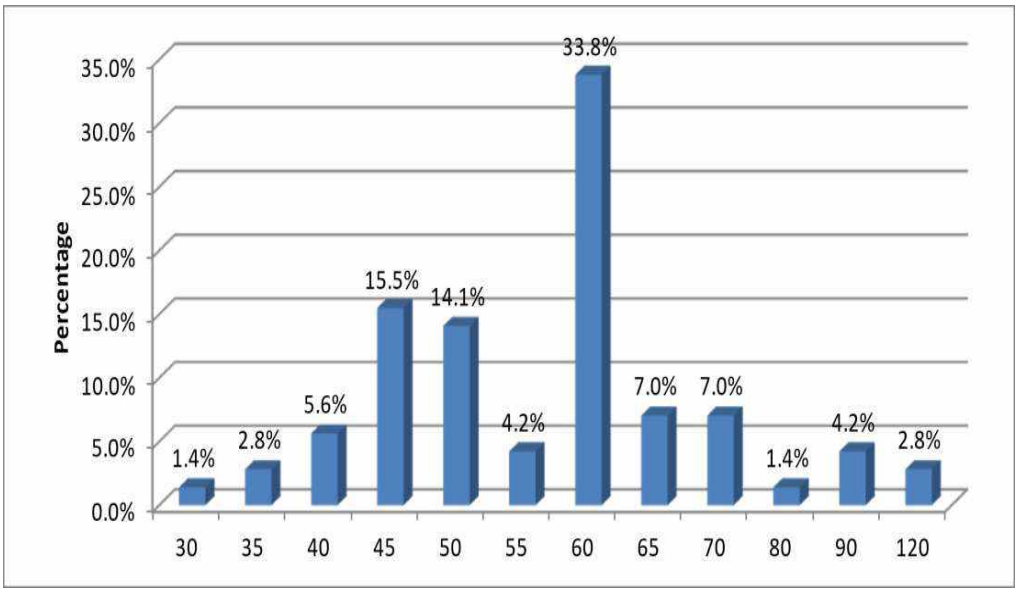
OPERATION TIME

The operation time had a variation ranging from 30 minutes to 120 minutes with a mean time of 58.10 minutes. Majority of cases, 55 of 71 (77.5%) were completed within one hour.

Table 13: Duration of surgery

Duration Of Surgery (Minutes)	No. of cases	Percentage
30	1	1.4%
35	2	2.8%
40	4	5.6%
45	11	15.5%
50	10	14.1%
55	3	4.2%
60	24	33.8%
65	5	7.0%
70	5	7.0%
80	1	1.4%
90	3	4.2%
120	2	2.8%
Total	71	100.0%

Figure 20: Duration of Surgery



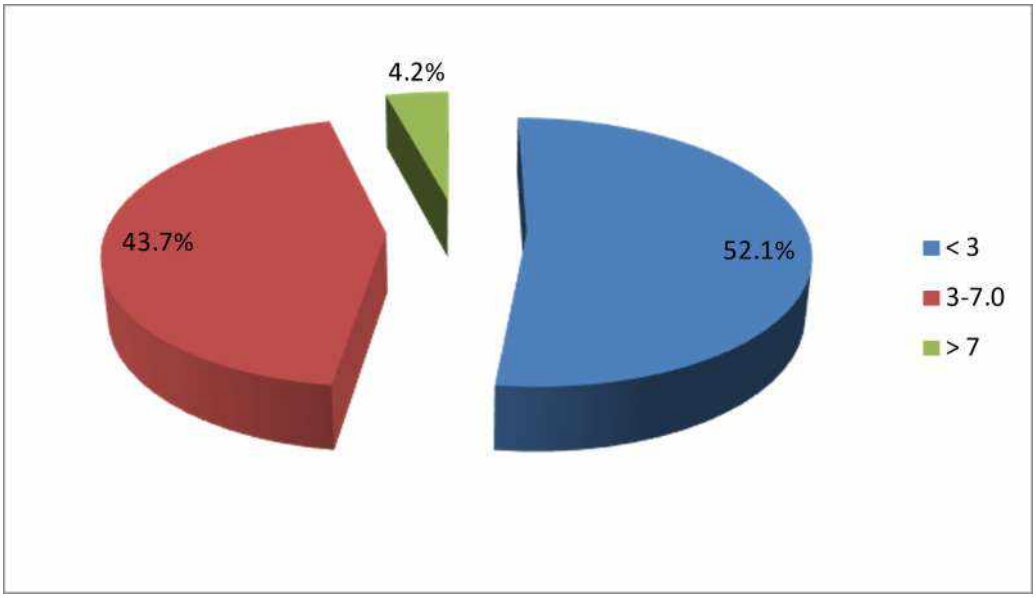
Hospital stay

In our study, most patients, i.e., 37 of 71 were discharged in less than 3 days of admission (52.1%) while 31 patients were discharged between 3 and 7 days (43.7%) and 3 were discharged after more than a week (4.2%).

Table 14: Duration of Hospital stay

Hospital stay	No. of cases	Percentage
< 3	37	52.1%
3-7.0	31	43.7%
> 7	3	4.2%

Figure 21: Duration of Hospital stay



Timing of ICG administration

70 patients were administered with ICG dye pre-operatively, 1 was not administered in view of history of iodine allergy. 62 of 70 (88.6%) patients were administered the dye 30 minutes prior to induction. No significant difference in term of visualization of anatomy was seen between the patients that were administered the dye at 15 and 30 minutes.

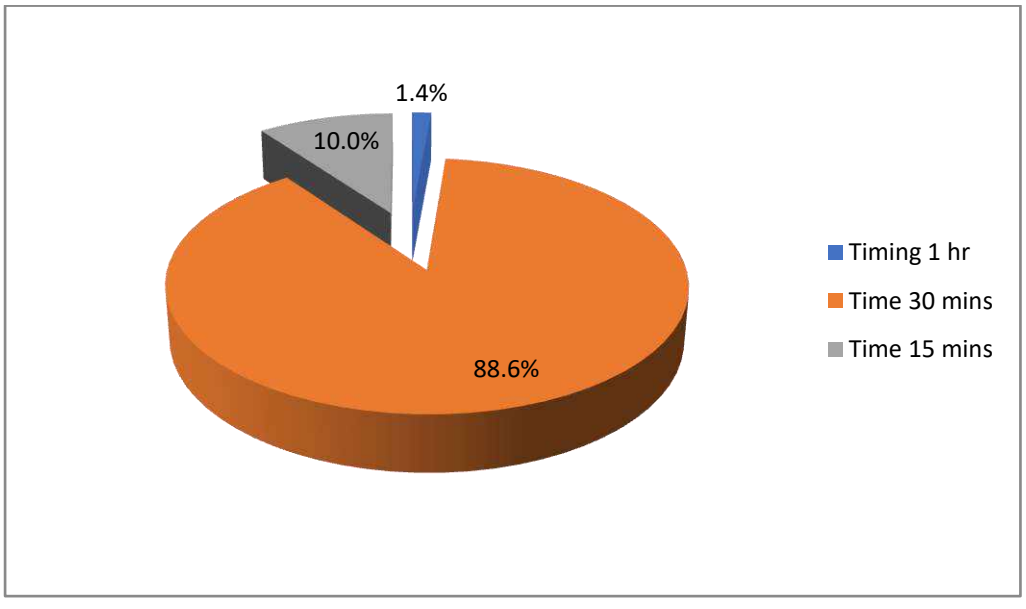
Table 15: Cases in which ICG used

DYE	No. of cases	Percentage
No	1	1.4%
Yes	70	98.6%
Total	71	100.0%

Table 16: Timing of administration of ICG

DYE TIME	No. of cases	Percentage
Timing 1 hr	1	1.4%
Time 30 mins	62	88.6%
Time 15 mins	7	10.0%
Total	70	100.0%

Figure 22: Timing of administration of ICG



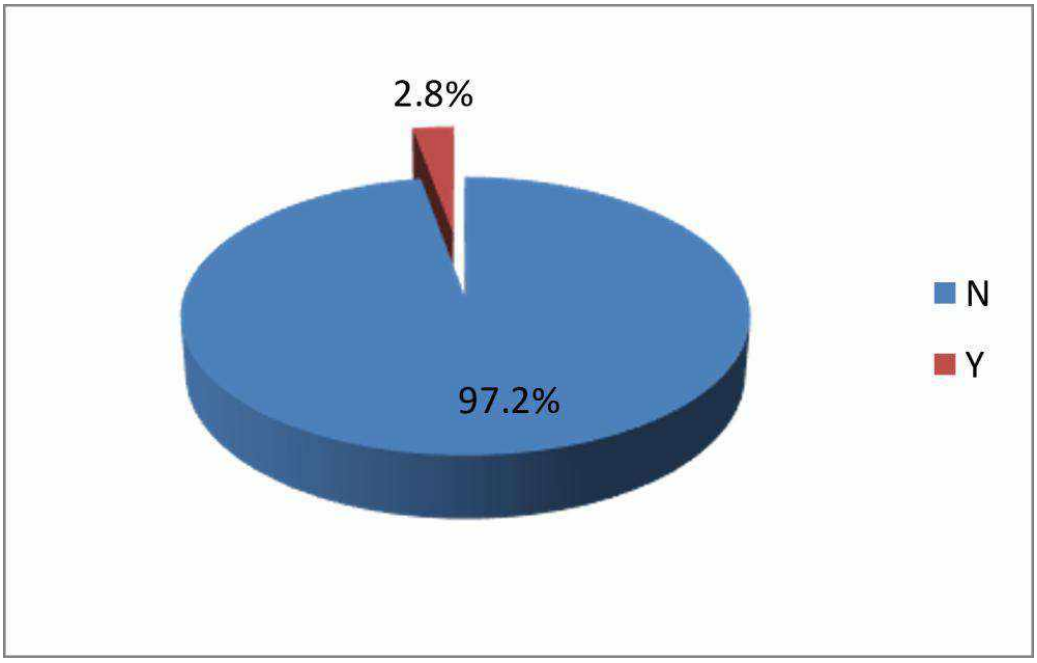
Adverse Reaction to ICG

2 patients had a reaction to ICG post administration, wherein one had a skin rash while the other had an arrythmia which settled without any intervention.

Table 17: Adverse reaction to ICG

Reaction To Icg	No. of cases	Percentage
No	69	97.2%
Yes	2	2.8%
Total	71	100.0%

Figure 23: Adverse reaction to ICG



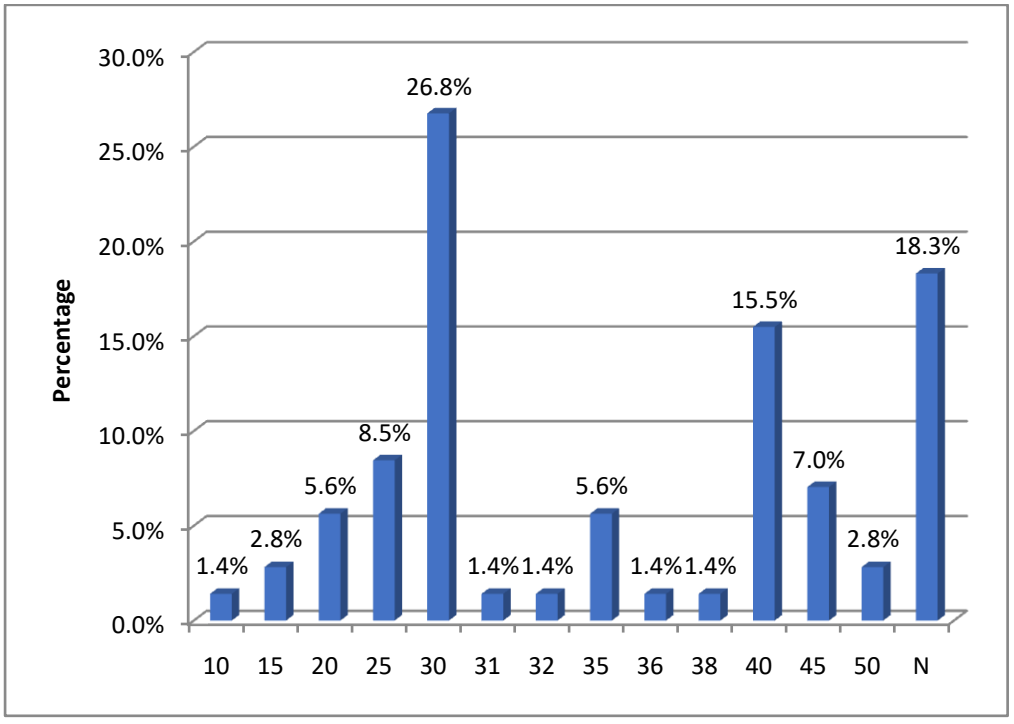
Timing of first visualization of Gall bladder

The gall bladder was visualized in 58 of 71 cases using ICG with a mean time of visualization of 32.45 minutes, ranging between 10 and 50 minutes. In majority of the cases (49/58) the gall bladder was visualized in between 25 and 45 minutes (69.01%). Of the cases, in which the GB was not visualized, 1 (1.4%)cases were that of acute calculous cholecystitis, 3 of acute gangrenous cholecystitis (4.2%), 1 (1.4%) patient had acute mild pancreatitis with peripancreatic collection, 1 had empyema GB(1.4%) and 3 had mucocele GB(4.2%).

Table 18: Time to GB visualization

Gall bladder visualization	No. of cases	Percentage
10 minutes	1	1.4%
15minutes	2	2.8%
20minutes	4	5.6%
25minutes	6	8.5%
30minutes	19	26.8%
31minutes	1	1.4%
32minutes	1	1.4%
35minutes	4	5.6%
36minutes	1	1.4%
38minutes	1	1.4%
40minutes	11	15.5%
45minutes	5	7.0%
50minutes	2	2.8%
Not visualized	13	18.3%
Total	71	100.0%

Figure 24: Time to first visualization of gall bladder



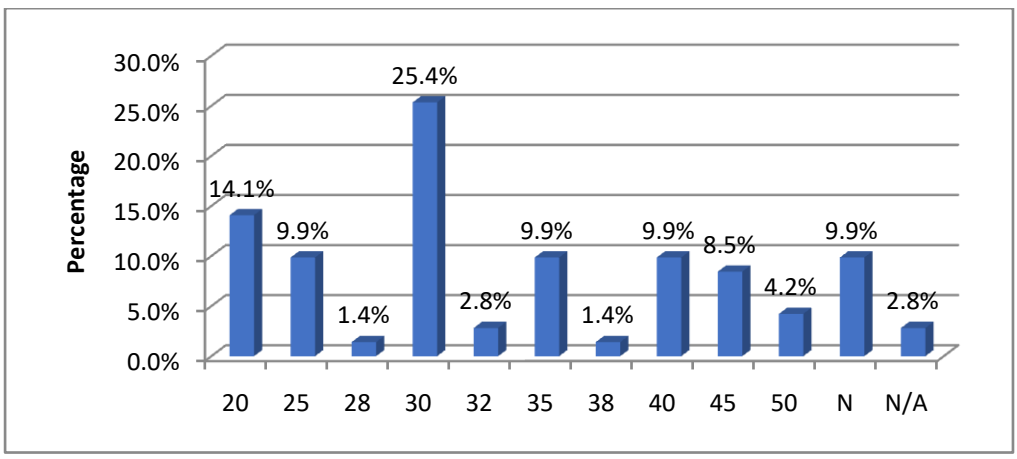
Timing of first visualization of Cystic Duct

The cystic duct was visualized in 62 of 71 cases using ICG with a mean time of visualization of 32.10 minutes, ranging between 20 and 50 minutes. In majority of the cases (53/62) the cystic duct was visualized in between 20 and 40 minutes (75.7%). Of the cases in which CD was not visualized, 1 (1.4%) patient had concomitant CBD stones, 3 (4.2%) patients had acute gangrenous cholecystitis, 1 (1.4%) had empyema GB, 1 (1.4%) had acute calculous cholecystitis and 2 (2.8%) had Mucocele GB.

Table 19: Time to Cystic duct visualization

Cystic duct visualization	No. of cases	Percentage
20 minutes	10	14.1%
25minutes	7	9.9%
28minutes	1	1.4%
30minutes	18	25.4%
32minutes	2	2.8%
35minutes	7	9.9%
38minutes	1	1.4%
40minutes	7	9.9%
45minutes	6	8.5%
50minutes	3	4.2%
N	9	12.67%
Total	71	100.0%

Figure 25: Time to first visualization of cystic duct



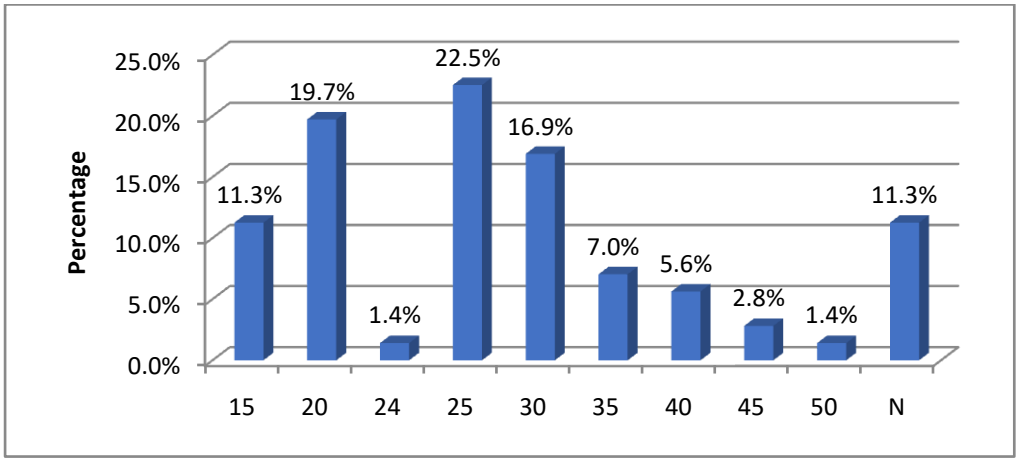
Timing of first visualization of Common Bile Duct

The common bile duct was visualized in 63 of 71 cases using ICG with a mean time of visualization of 26.33 minutes, ranging between 15 and 50 minutes. In majority of the cases (51/58) the CBD was visualized in between 15 and 30 minutes (71.8%). Of the cases in which CBD was not visualized, 3 (4.2%) patients had acute gangrenous cholecystitis, 1 (1.4%) had empyema GB, 1 (1.4%) had acute calculous cholecystitis and 3 (4.2%) had Mucocele GB.

Table 20: Time to CBD visualization

CBD VISUALIZATION	No. of cases	Percentage
15 Minutes	8	11.3%
20Minutes	14	19.7%
24Minutes	1	1.4%
25Minutes	16	22.5%
30Minutes	12	16.9%
35Minutes	5	7.0%
40Minutes	4	5.6%
45Minutes	2	2.8%
50Minutes	1	1.4%
N	8	11.3%
Total	71	100.0%

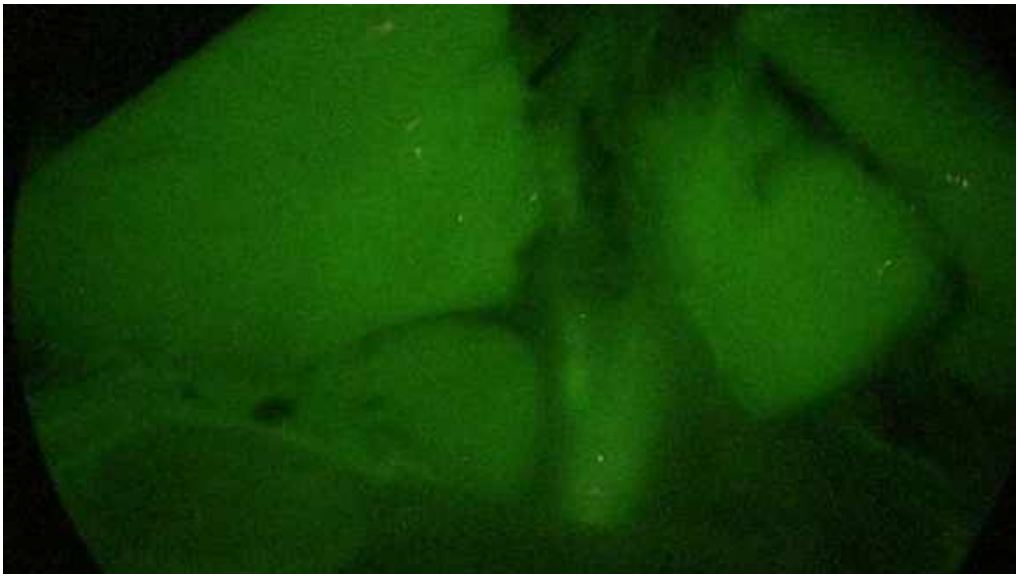
Figure 26: Time to first visualization of CBD



Significant Anatomic Findings identified during ICG-IOC

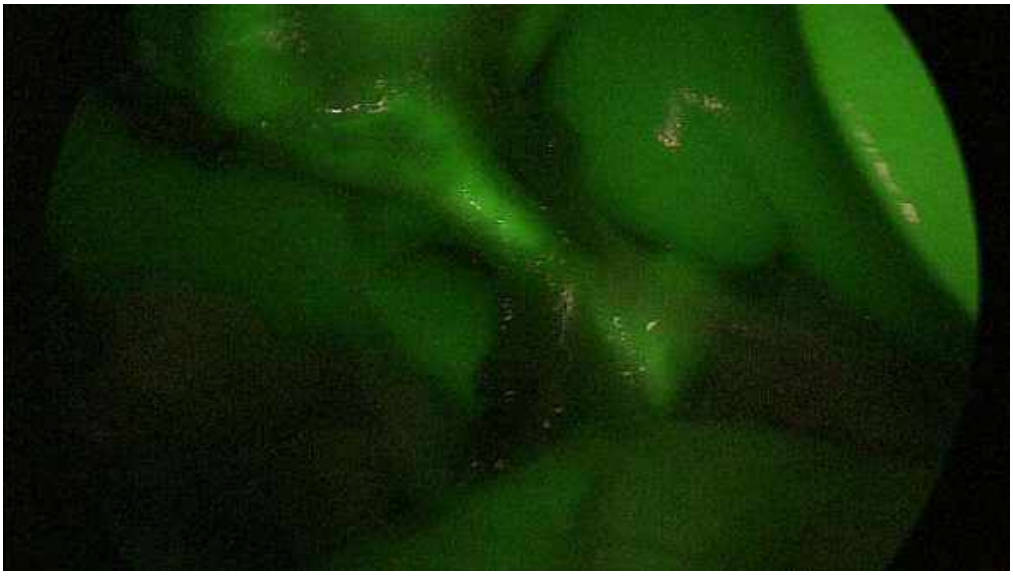
Of the 70 patients undergoing lap. Cholecystectomy with NIR-ICG IOC, 1 patient had an identified short cystic duct (1.4%), 2 patients had a parallel union of the CD with CBD(2.8%), 2 patients had low medial insertion of CD with CBD (2.8%) and 3 patients had CBD stones 4.2%).

Short cystic duct



Parallel union of CD with CBD

Dilated CBD



Low Medial insertion of CD

CBD stones identified in IOC

CBD injury

One case, which underwent surgery for acute mild gall stone induced pancreatitis, had a class E2 CBD injury (1.4%), which was identified using ICG intra-operatively.

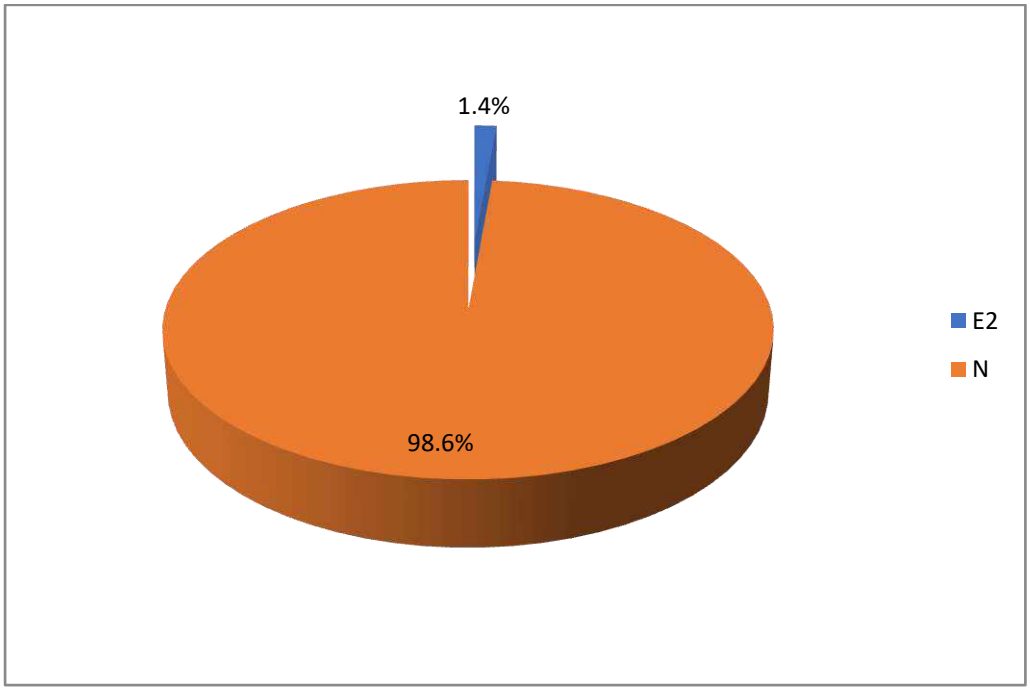
Table 21: Incidence of CBD injury

CBD INJURY	No. of cases	Percentage
NO	70	98.6%
YES	1	1.4%
Total	71	100.0%

Table 22: Class of CBD injury

CLASS OF CBD INJURY	No. of cases	Percentage
E2	1	1.4%
NONE	70	98.6%
Total	71	100.0%

Figure 27: Incidence of CBD injury



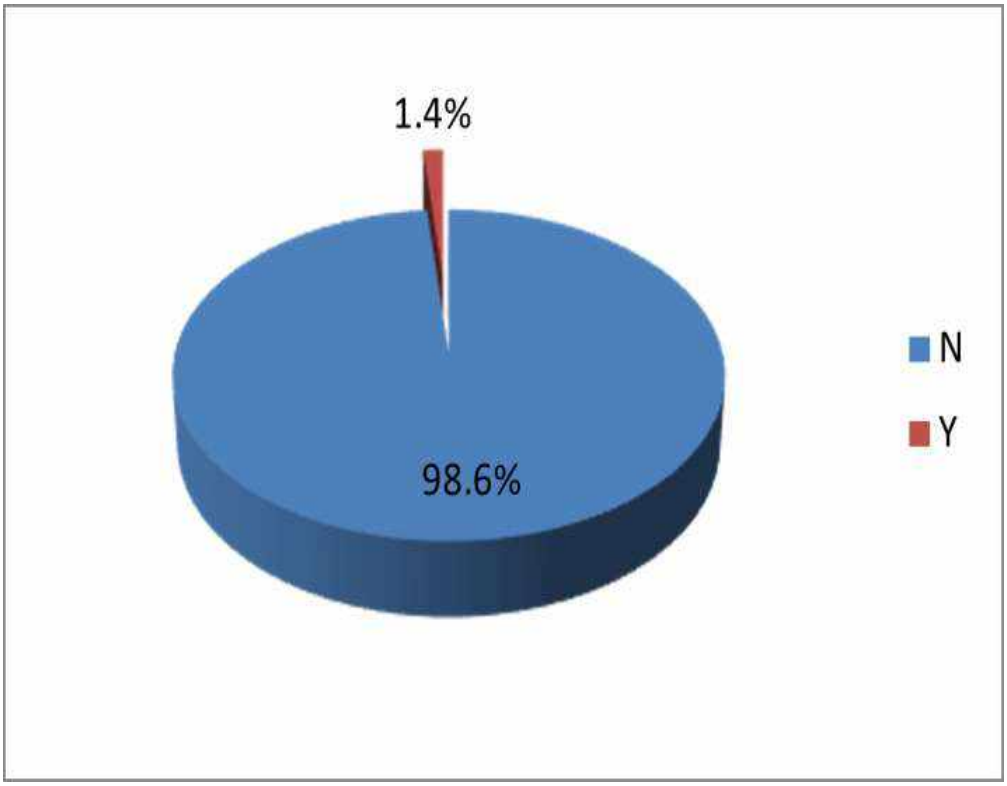
Conversion to open Surgery

One case with class E2 CBD injury was converted to open.

Table 23: Conversion to open surgery.

Conversion to open	No. of cases	Percentage
No	70	98.6%
Yes	1	1.4%
Total	71	100.0%

Figure 28: Conversion to open surgery.



Discussion

A prospective observational study was conducted in 71 patients with different indications for undergoing lap. Cholecystectomy. Of the 71 patients, the most common symptom with which patients presented to the hospital was pain abdomen, in 68 of 71 patients (95.8 %). Around 20 patients had complaints of nausea (28.%) and an equal number of patients had associated vomiting (28.2%) with a significant overlap. 6 patients presented with jaundice (8.5%) while appetite loss was noted in 17 patients (23.9%) and fever in 10 (14.1%). In one patient (1.4%), we observed a sub-capsular hematoma in the liver which was followed post-operatively using USG and managed conservatively.

Age Distribution

In our study the mean age of the patients was 48.2 years, with a range between 18 and 84 years with 57 of 71(80.3%) patients being in the 4^{th} to 7^{th} decades of life, with nearly half the (33/71) patients being over above 50 years of age (46.5%). In a cohort study by Ambe et al, 70 patients were randomized to undergo LC with and without usage of ICG. In their studies the mean age of patients undergoing LC with ICG was 56 years and in patients who underwent LC without ICG was 61 years.[14] In a study by Hiwatashi et al in 2018, they recruited 65 patients with a mean age of 61.34 years with a range between 32 and 90 years of age.[17] In a study by Dieuwertje A. van Dam et al in 2014, they included patients between the ages 18 and 80 years with a mean age of 49.7 +/- 16.7 years.[35]

Sex Distribution

In our study, there was a female predominance among the patients, with a male to female ratio of 24:47. In a study by Hiwatashi et al in 2018, they had almost equal participation by both sexes, in a ratio of 31:34(M:F).[17] In a study by Dieuwertje A. van Dam et al in 2014, they also had a female predominance with a Male to female ratio of 9:21. [35]

Indication of Surgery

In our study, most patients underwent surgery for gall stone disease, in 34 of 71 patients (47.9%), of which 7 had concomitant CBD stones

(9.9%). 23 patients were operated for chronic cholecystitis (32.4%). 8 patients had acute cholecystitis (11.2%). In the study by Ambe et al, 58 patients (82.9%) underwent surgery for symptomatic gall stone disease while 12 (17.1%) had acute cholecystitis.[14] In their study among 20 patients, Ankersmit M. et al, two patients were excluded later because of early conversion to open procedure in view of dense adhesions as a result of acute cholecystitis. Of the rest 18, 3 had biliary pancreatitis, 7 had acute cholecystitis, and 7 had concomitant choledochiolithiasis.[19] In the study Pesce et al, 50 patients underwent LC with ICG-IOC of which 84 % patients underwent the procedure for symptomatic gall stone disease while 8% patients underwent the same for chronic cholecystitis.[45] In their study, Tsutsui et al, administered 25 mg of ICG at different time prior to surgery in 72 patients after randomization and of these 2 patients had chronic cholecystitis, 2 had adenomyomatosis, 4 had GB polyps while the rest 64 had symptomatic gall stones.[37]

History of Iodine Allergy

In our study, one patient underwent LC but could not be included in the intervention group, in view of previous history of iodine allergy. In the study of Ishizawa et al, 52 patients were evaluated, amongst which 6 patients could not be studied with ICG intra-operative cholangiograhy in view of iodine allergy in 5 and one being a known case of CRF.[2]

Previous history of pancreatitis

In our study, 2 patients (2.8 %) underwent LC during the index admission of Acute biliary pancreatitis, of which one case was converted to open in view of CBD injury, 2 patients were follow up cases of acute severe pancreatitis and underwent interval surgery. In the study by Ankersmit M. et al, Three patients suffered from biliary pancreatitis, one of whom had a complicated history of necrotizing biliary pancreatitis with renal failure and neuropathy, resulting in a prolonged stay at the intensive care unit before surgery.[19]

Duration of Surgery

The mean duration of study in our study was 58.10 minutes, with a range between 30 and 120 minutes. In a study done on Lap. Cholecystectomy and its complications during the same duration in

DMC&H, Ludhiana, the average duration of the surgery was 94.438 minutes, ranging between 25 and 225 minutes. In their study on 65 patients, Hiwatashi et al, among 61 patients wherein CBD was identified using ICG, mean duration of surgery was 130.62 minutes while in 4 patients, where CBD was not visualized, mean duration of surgery was 165.75 minutes.[17] In their study on 18 patients, Ankersmit et al, among 13 patients wherein CBD was identified using ICG, mean duration of surgery was 75 minutes while in 5 patients, where CBD was not visualized, mean duration of surgery was 90 minutes.[19]

Dose and Timing of ICG administration

In our study, all the patients were injected with 5 mg of ICG pre-operatively and majority (62/70) of the patients in this study were administered the dye about 30 minutes prior to surgery (88.6%), while 7 patients were administered the dye 15 minutes prior to surgery (10%) and one patient was given the dye 1 hour prior to surgery (1.4%). In the study by Zarrinpar et al, ICG was administered intravenously by the study coordinatoror the anaesthesiologist at the following doses: 0.02, 0.04, 0.08, and 0.25 mg/kg. The timing of the injection also systematically varied: 10 ± 3 minutes, 45 ± 15 minutes, and 3 ± 1 hours prior to anticipated visualization and the operating surgeon was blinded to the dose and timing of ICG administration. They concluded that a dose as low as 0.02 mg/kg was enough for visualization of the biliary anatomy given enough time.[32] In their study by Dieuwertje A. van dam et al, 30 patients were administered ICG dye, immediately after induction of anaesthesia and surgery started 10 minutes after.[35] In the study by Tsutsui et al, 72 patients were randomized into groups that were administered 25 mg of ICG dye immediately before surgery or at 3,6,9,12,15,18 and 24 hours prior to surgery. They concluded that the proportion of cases in which two or more evaluators classified the visibility of the gallbladder and bile ducts as grade A, first increased with the 12-h group, reached a peak in the 15-h group, and decreased thereafter and also based on contrast to background ratios, concluded that ICG is best administered at 15 h prior to surgery.[37]

Adverse reaction to ICG

In our study, 2 patients had an adverse reaction to ICG, wherein one developed a minor skin rash with pruritus limited to the trunk and one patient developed a tachy-arrythmia post induction of anaesthesia, which then settled spontaneously. Hope-Ross M. et al in 1993 reported 3 (0.15%) mild adverse reactions, 4 (0.2%) moderate adverse reactions and 1(0.05%) severe adverse reactions among 1923 ICG video angiographies performed.[46] Benya R. et al on 1989 reported a case of a 63 years old patient who was planned for cardiac biopsy with ICG administration prior to procedure, who developed urticaria, nausea, breathlessness, wheeze and headache which was managed with diphenhydramine, methylprednisolone and metaprotenerol nebulization.[47]

Timing of GB visualization

In our study, the gall bladder was first visualized after administration of ICG with a mean of 32.45 minutes, ranging between 10 and 50 minutes. In their study, Tsutsui et al, determined that GB/liver luminance intensity ratio increased to more than 1 in the 6,12,15,18 and 24 hour groups while decreasing to less than 1 in the 9 hour group with a significant difference between the 0 hour and the 15, 18 and 24 hour groups.[37]

Timing of CD visualization

In our study the CD was visualized in 62 of 71 patients (87.3%) with a mean time of 32.10 minutes, ranging between 20 and 50 minutes. In their study by Ishizawa et al, cystic duct was identified in all 52 of 52 cases before dissection of calot;s triangle.[2]

In their study by Pesce et al, the CD was identified by FC in 43(86%) and 45 of 50 patients (90%) before and after Calot'sdissection respectively.[11] In the study by Hiwatashi et al, they visualized CD in 54 of 65 patients undergoing LC and factors associated with non-visualization of the CD were higher CRP, higher WBC, higher Conversion rates to open, higher rates of acute cholecystitis.[17] In their study by Ankersmit MD et al, at CVS, the CD could be identified inall

18 patients using conventional white light, whereas using ICG-NIR imaging, the CD was identified in 13 of 18patients.[19]

Timing of CBD visualization

In our study the CBD was visualized in 63 of 81 (88.7%) patients, with a mean duration from start of surgery being 26.33 minutes, ranging between 15 and 50 minutes. In their study by Pesce et al, the CHD and the CBD were successfully identified in 12 (24%) and 33 patients (66%) before Calot's dissection respectively and in 26 (52%) and in 47 patients (94%) after complete Calot's dissection respectively.[11] In the study by Hiwatashi et al, the ICG cholangiography using laparoscopic fluorescence imaging systems showed 61 patients (93.8%) in the identified CBD group and 4 patients (6.2%) in the not identified CBD group. All cases of the not identified CBD group were included in the not identified CD group.[17] In their study by Ankersmit MD et al, at CVS, using white light, the CBD could be identified in only 3 of 18 patients. Using ICG-NIR imaging, the CBD could be identified in 7 of 18 patients, all of whom also showed a fluorescent cystic duct.[19]

Complications

In our study, one patient of 71 had a CBD injury, class E2, for which the case was converted to open and managed with primary repair over CBD stent already in situ.

Summary and Conclusion

This prospective observational study was conducted on 71 patients with various indications for undergoing Laparoscopic Cholecystectomy with intra-operative cholangiography using ICG, in the department of surgery at Dayanand Medical college and hospital, Ludhiana during June 2020 to November 2021 and followed up till discharge from the hospital. All the patients underwent LC with 4 port technique using ICG dye administered pre-operatively.

The following observations were made: -

1. The mean age of the patients was 48.20 years.
2. There was a female predominance with 47 (66.2%) female patients and 24(33.8%) male patients.
3. 23.9% (17) patients had Type-II Diabetes Mellitus, 18.3 %(13 patients) of the patients had Hypertension and 8.5 %(6) had a co-existing Cardiac disease.
4. 1 patient had previous history of iodine allergy (1.4%).
5. 2 patients were operated during their index admission of acute biliary pancreatitis and 2 were follow up case of acute severe pancreatitis.
6. The mean duration of surgery was 58.10 minutes. The mean duration of hospital stay was 6 days with 52.1% patients being in less than 3 days group.
7. The dye was administered at 15 minutes prior to surgery in 7 of 71 patients (10 %), at 30 minutes in 62 of 71(88.6%) patients and at 1 hour in 1 patient, without any significant difference between the quality of images obtained on IOC between the two.
8. Two patients had an allergic reaction to ICG.
9. The mean time of first visualization of the gall bladder was 32.45 minutes, of the cystic duct was 32.10 minutes and of the CBD was 26.33 minutes.
10. One patient suffered a Class E2 CBD injury during the surgery, for which the surgery was converted to open.

Thus, through our study we conclude that near infrared imaging based intra-operative cholangiography using Indocyanine Green dye during Lap. Cholecystectomy is a useful method of visualizing the biliary ductal anatomy and its anatomical variations during the surgery and in thus helping to prevent injury to the CBD and can be done in any patient without a previous history of allergy to iodine, without significantly adding to the duration of surgery. The dye can be administered conveniently as an intravenous injection at a dose of 5 mg injected 15 to 30 minutes prior to induction of anaesthesia. We observed that the CBD and cystic duct were not clearly visualized on NIR-ICG IOC in cases with significant inflammatory changes like acute cholecystitis, biliary pancreatitis and empyema GB. In cases with Cirrhosis, the ductal anatomy was not clearly visualized likely due to delayed excretion of ICG from the hepatocytes. The imaging method also helped us identify CBD stones in a few cases.

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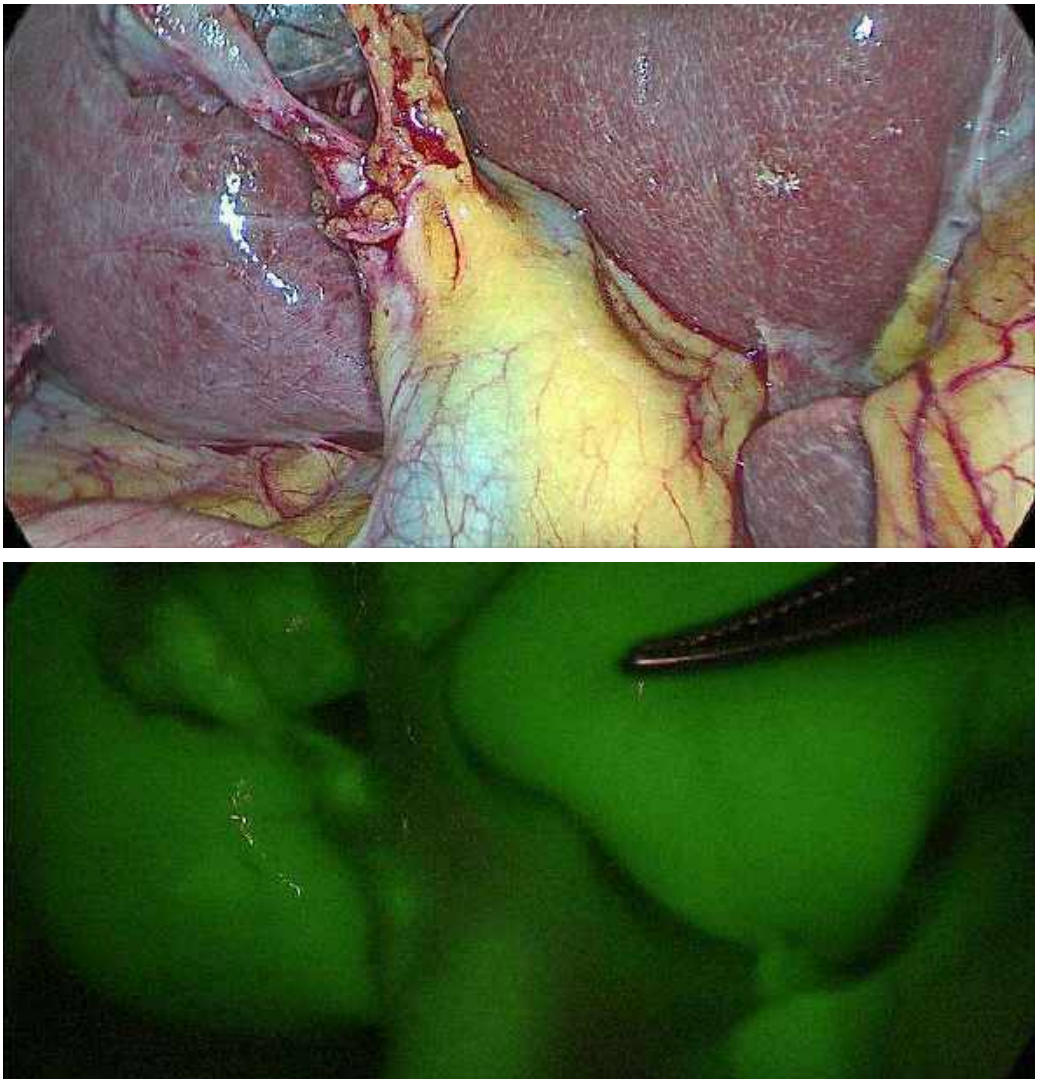
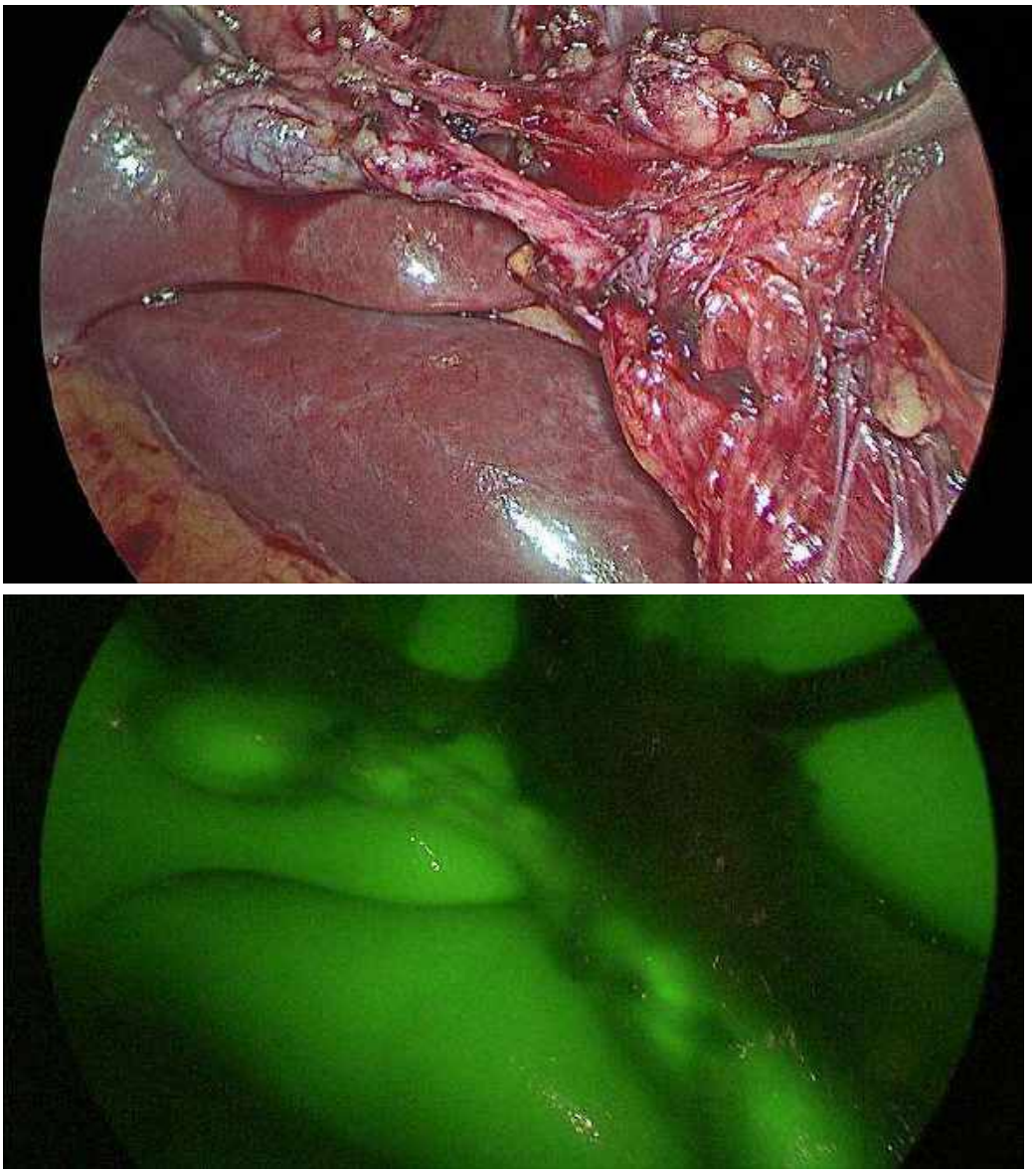
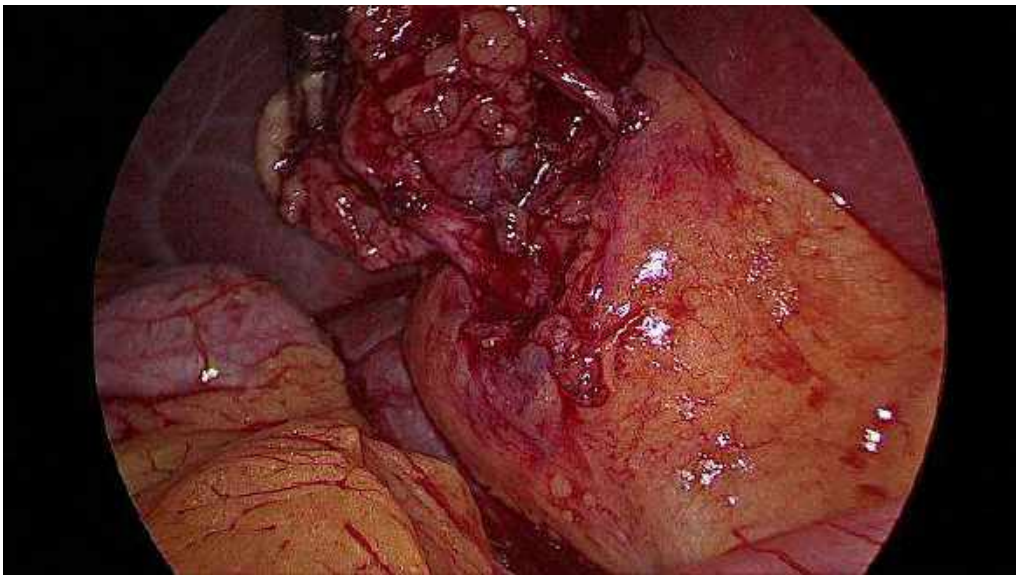


CASE 1:- NORMAL BILIARY ANATOMY AS VISUALIZED AFTER CALOT'S DISSECTION ON REAL TIME IMAGING AND NIR-ICG INTRA-OPERATIVE CHOLANGIOGRAPHY

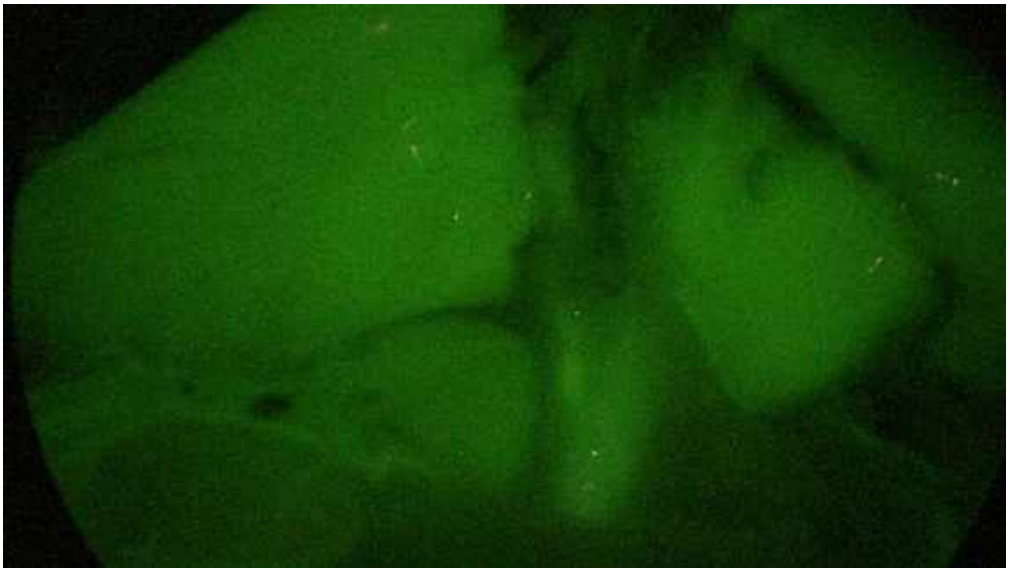
CASE 2:- SHORT CYSTIC DUCT



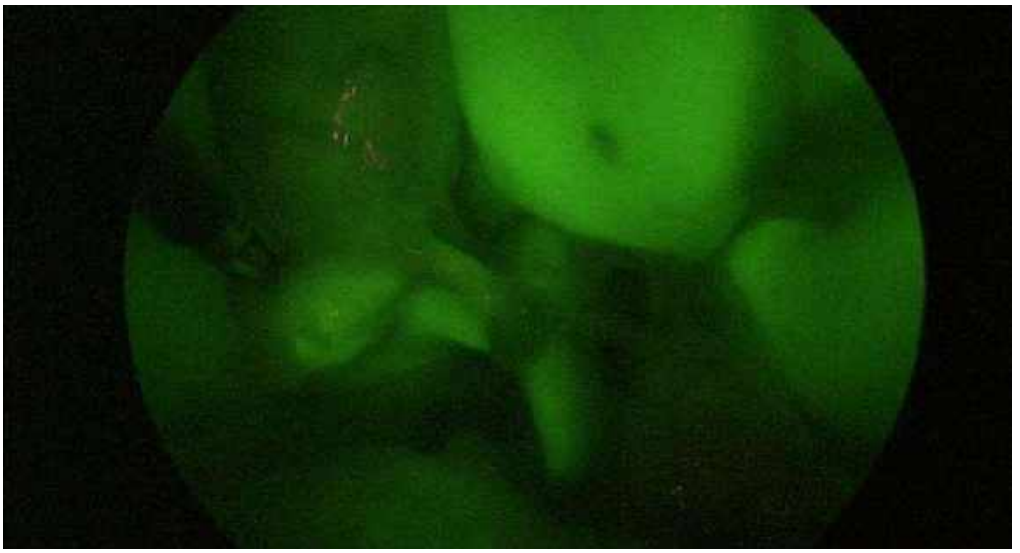
CASE 3:- DENSE ADHESIONS AROUND CALOT'S TRIANGLE AS SEEN ON REAL TIME AND NIR IMAGING

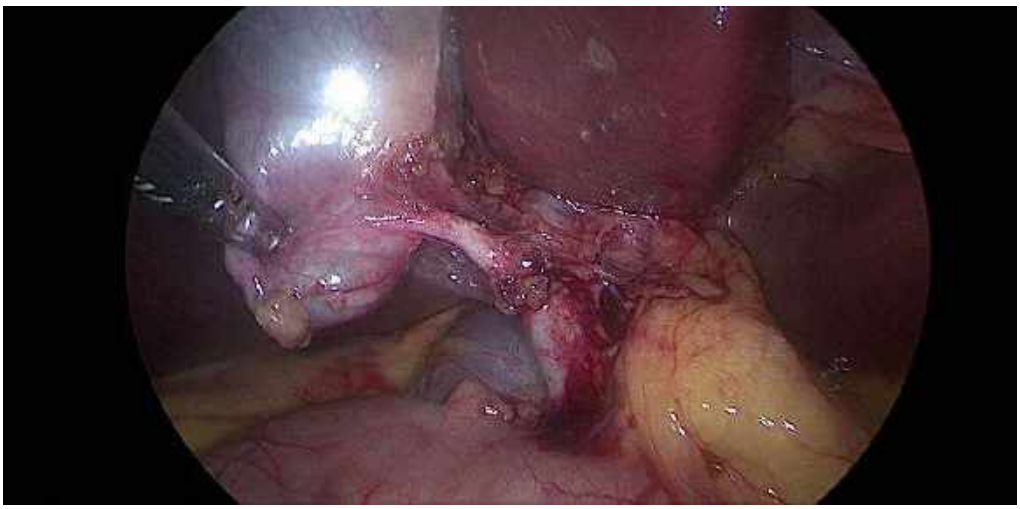


CASE 4:- DENSE ADHESIONS AROUND THE CALOT; S WITH A LONG CYSTIC DUCT.

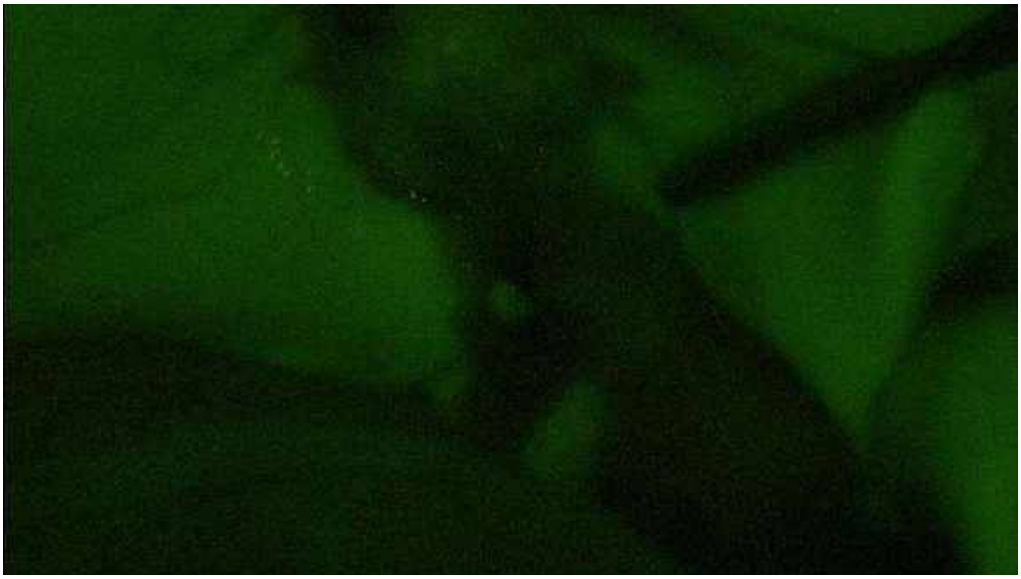


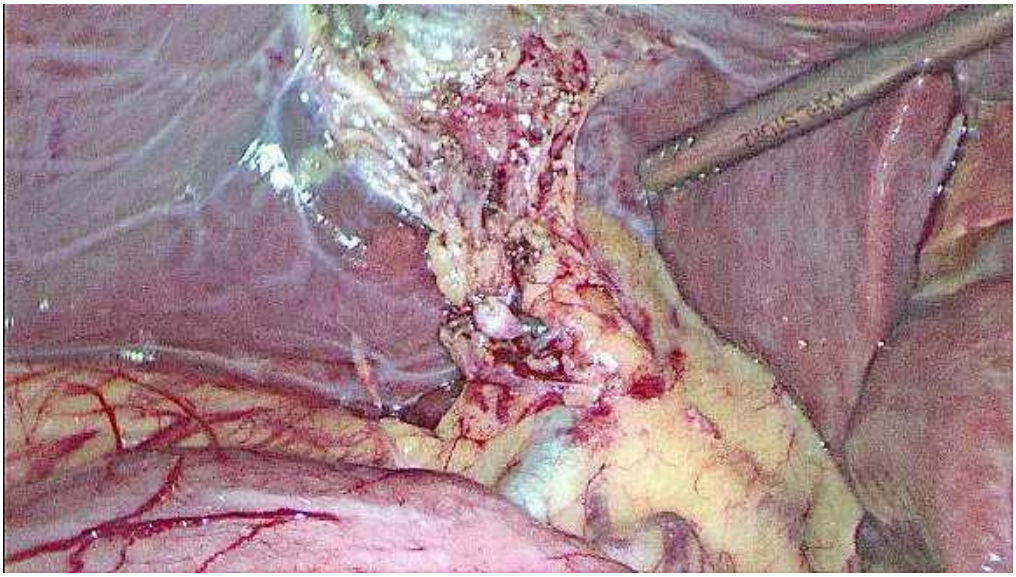
CASE 5:- ALMOST PARALLEL UNION OF THE CD WITH CBD. VISUALIZATION OF CD, CHD AND CBD.



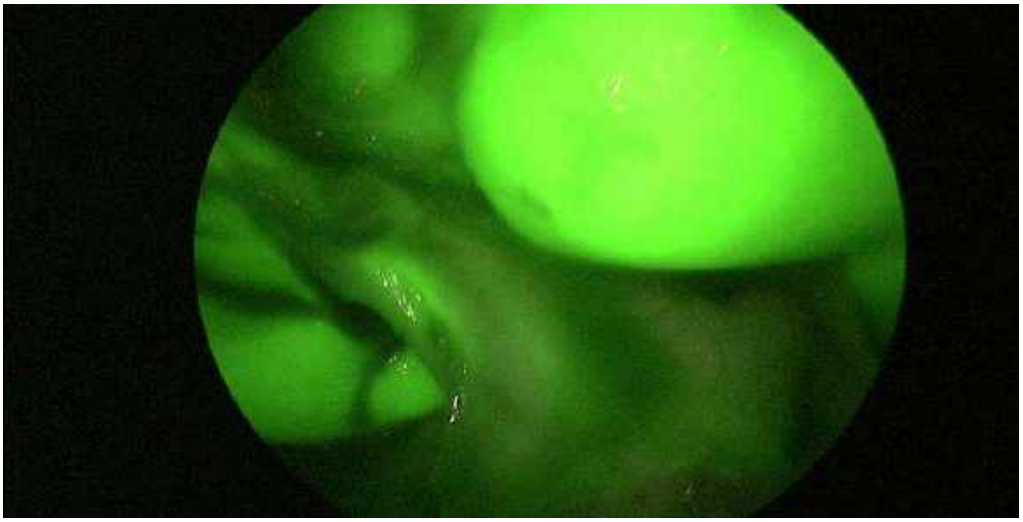


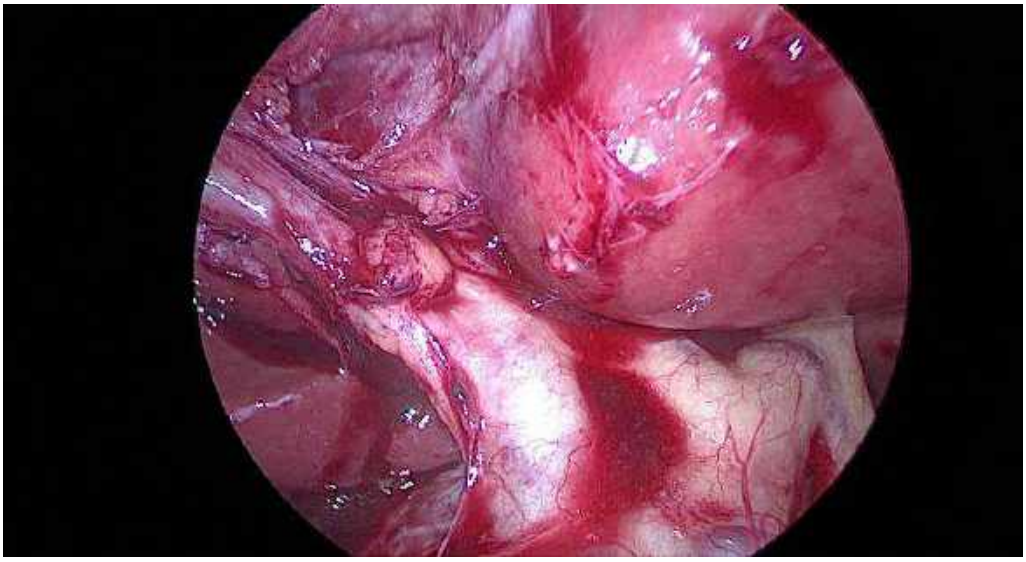
CASE 6:- VISUALIZATION OF THE CD, CHD AND CBD



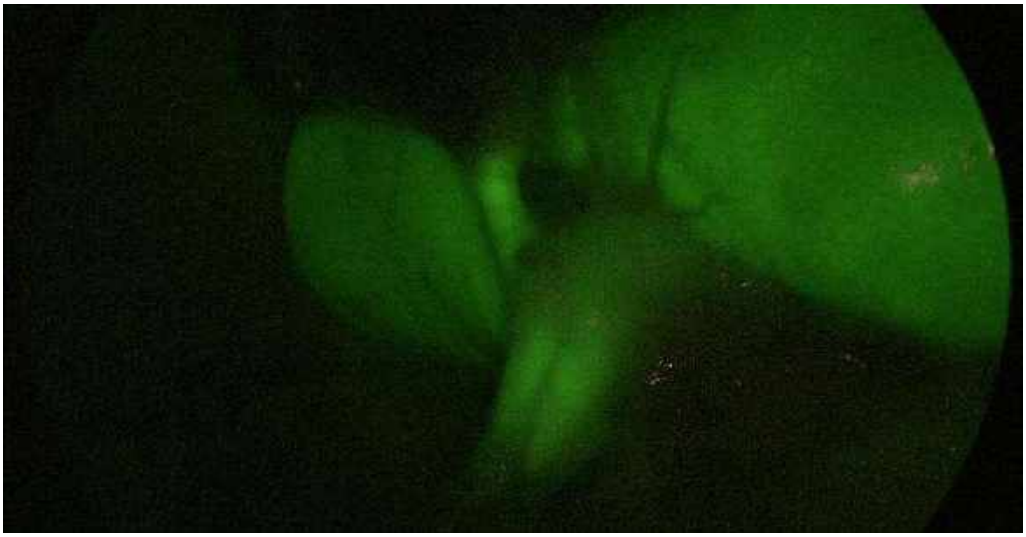


CASE 7:- DUE TO DENSE ADHESIONS, PARTIAL VISUALIZATION OF THE DUCTAL ANATOMY

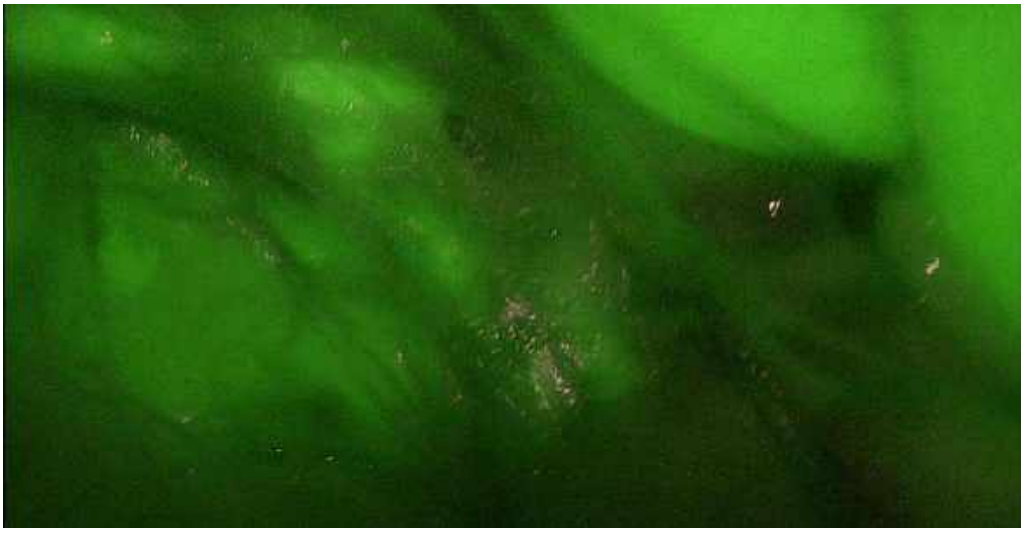




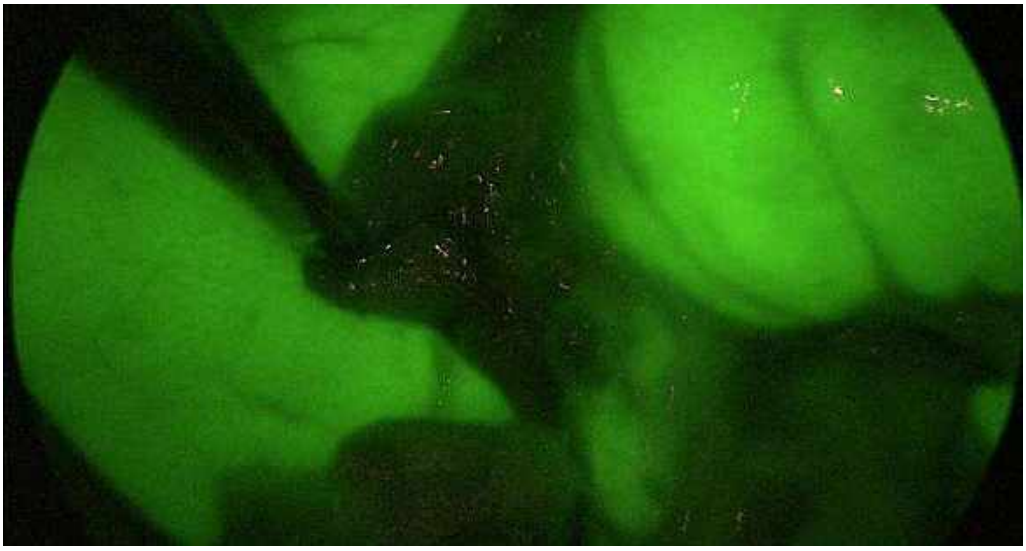
CASE 8:- ALMOST PARALLEL UNION OF THE CD WITH CBD. DUE TO DENSE ADHESIONS, PARTIAL VISUALIZATION OF THE CBD



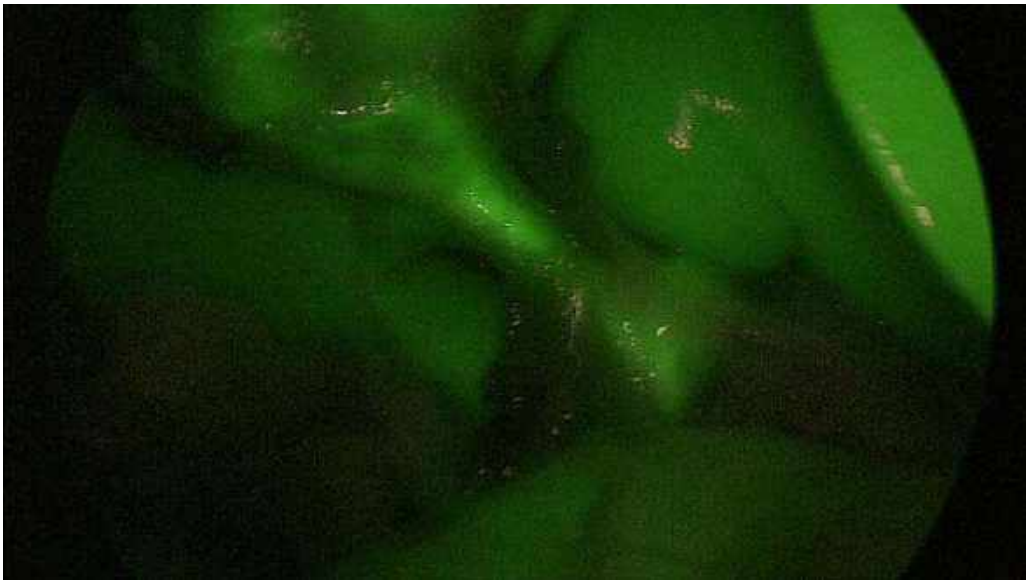
CASE 9:- DILATED CBD



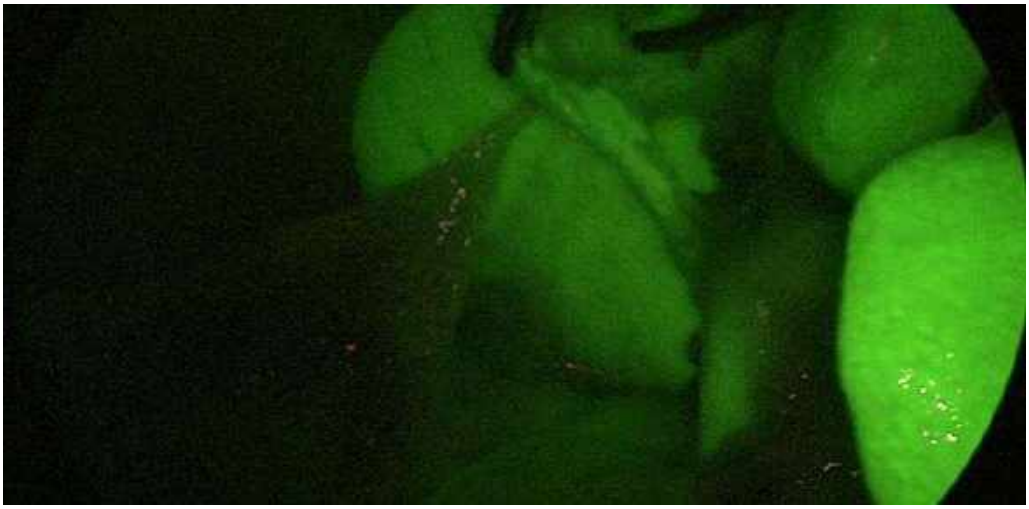
CASE 10:- DENSE ADHESIONS AROUND CD AND CBD

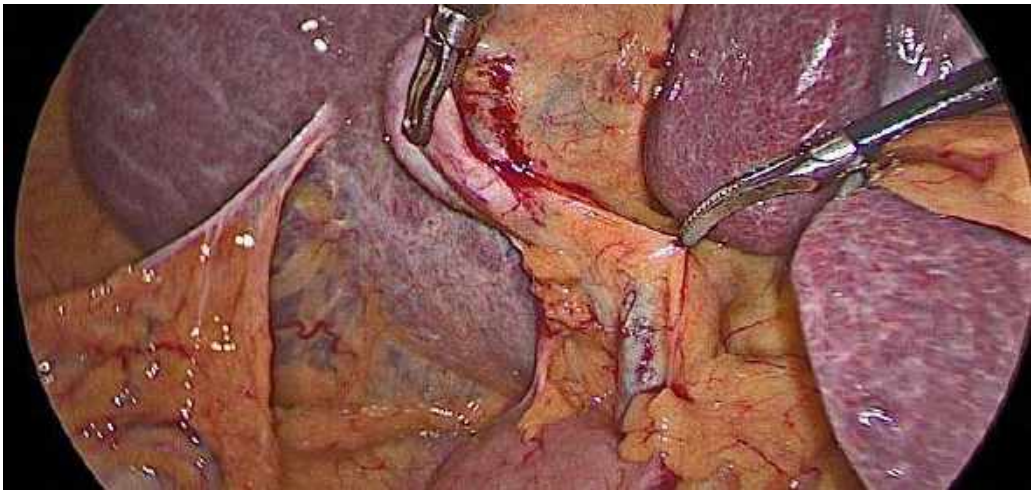


CASE 11:- DILATED CBD WITH DENSE ADHESIONS AROUND CALOT'S WITH NON-VISUALIZATION OF CD.

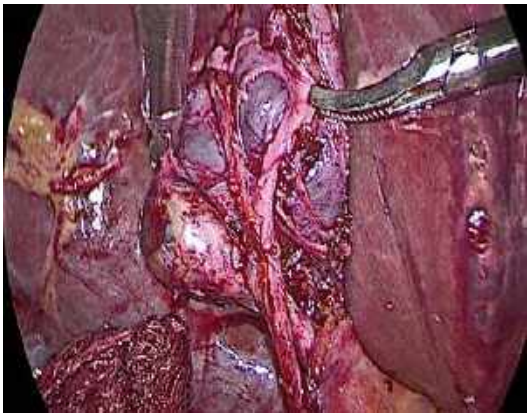
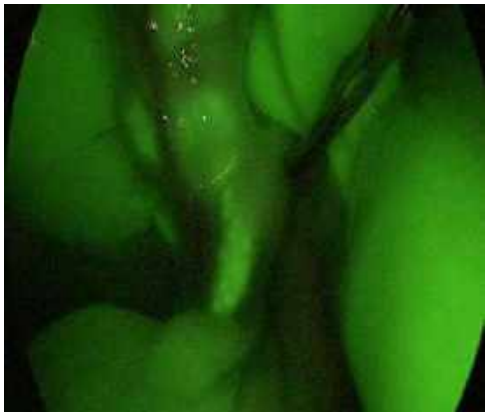
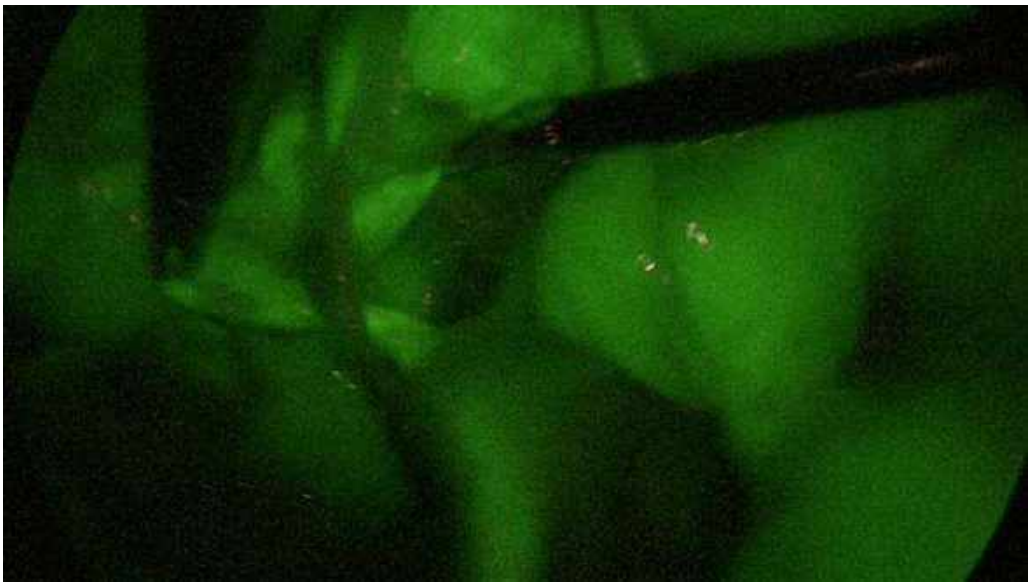
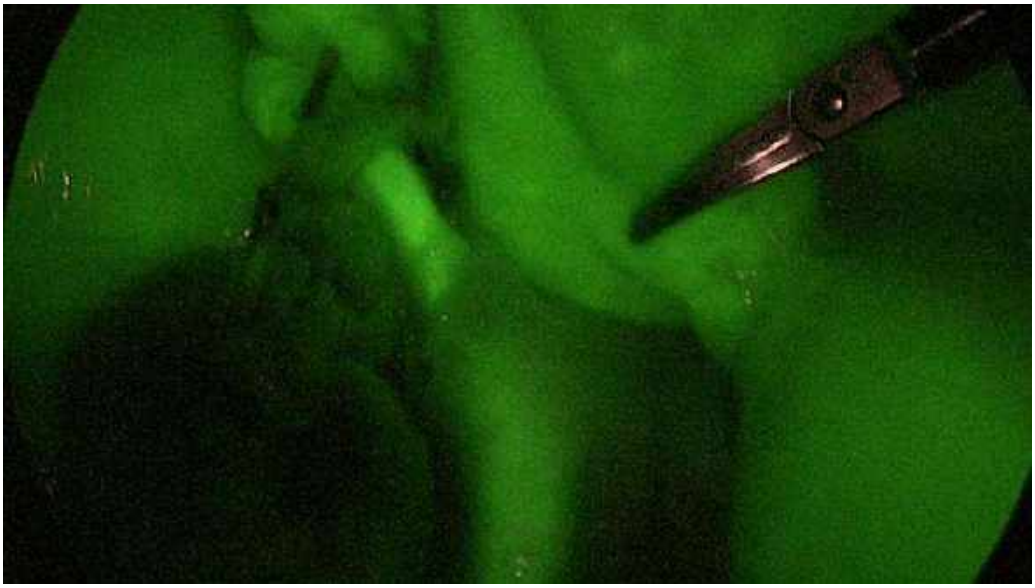


CASE 12:- LOW MEDIAL INSERTION OF CD INTO CBD. VISUALIZATION OF CD, CBD AND CHD.

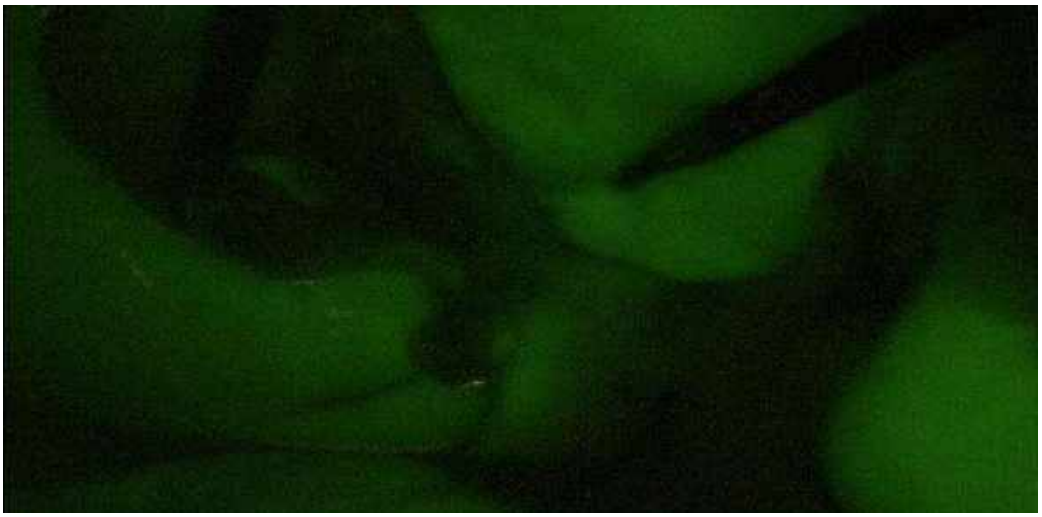


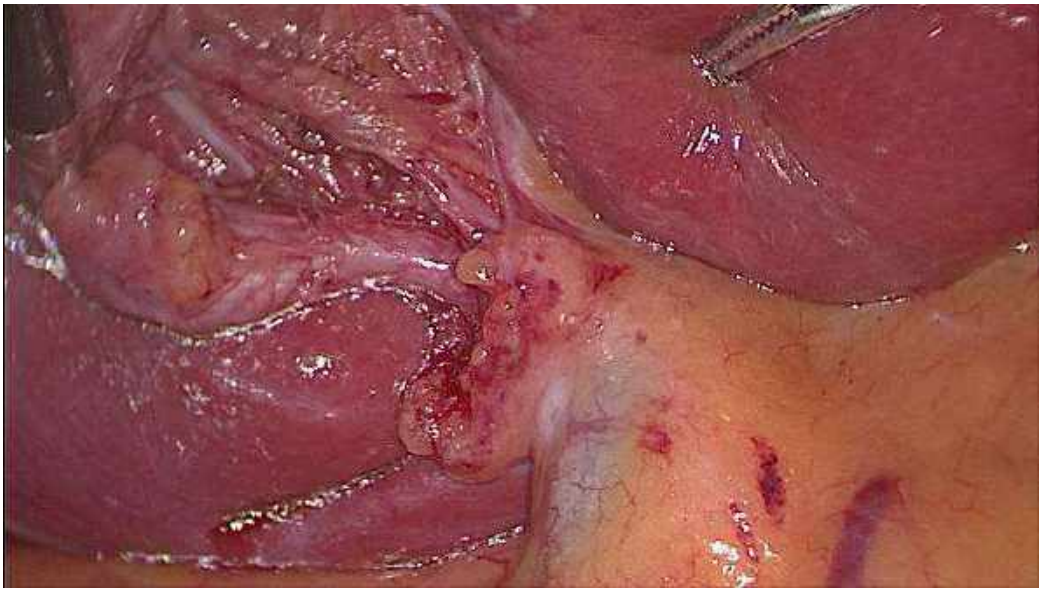


CASE 13:- VISUALIZATION OD CD, CBD AND CHD

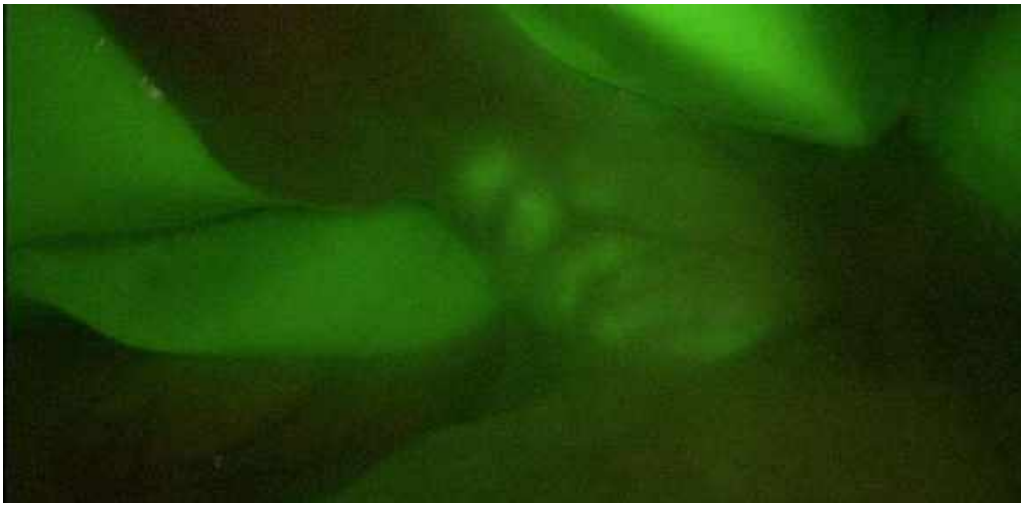





CASE 14:- ARTERY BIFURCATIONG OVER ANTERIOR WALL. SLUDGE PRESENT IN CBD. CBD STONES/SLUDGE PRESENT.

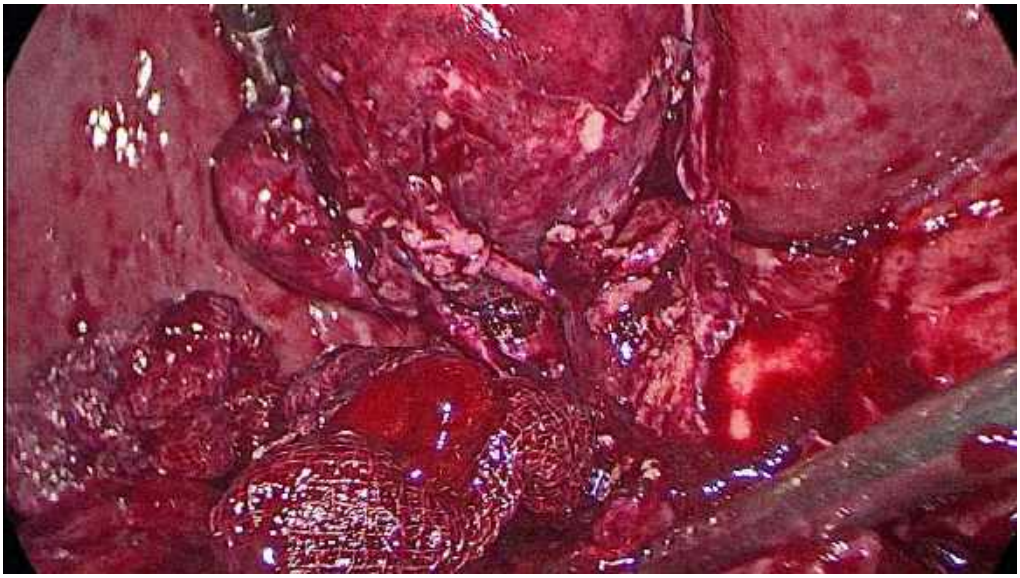




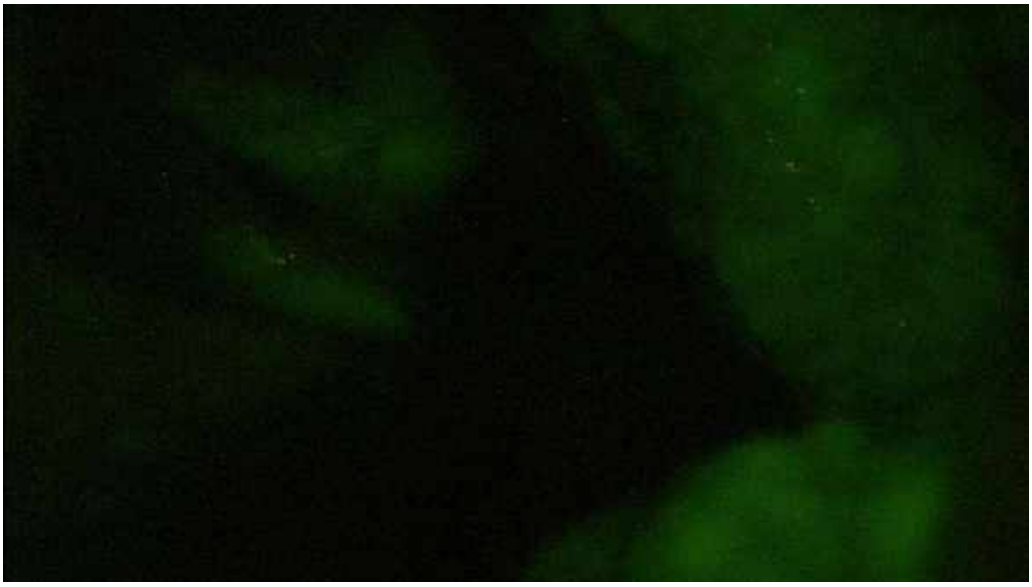
CASE 15:- LOW MEDIAL INSERTION OF CD



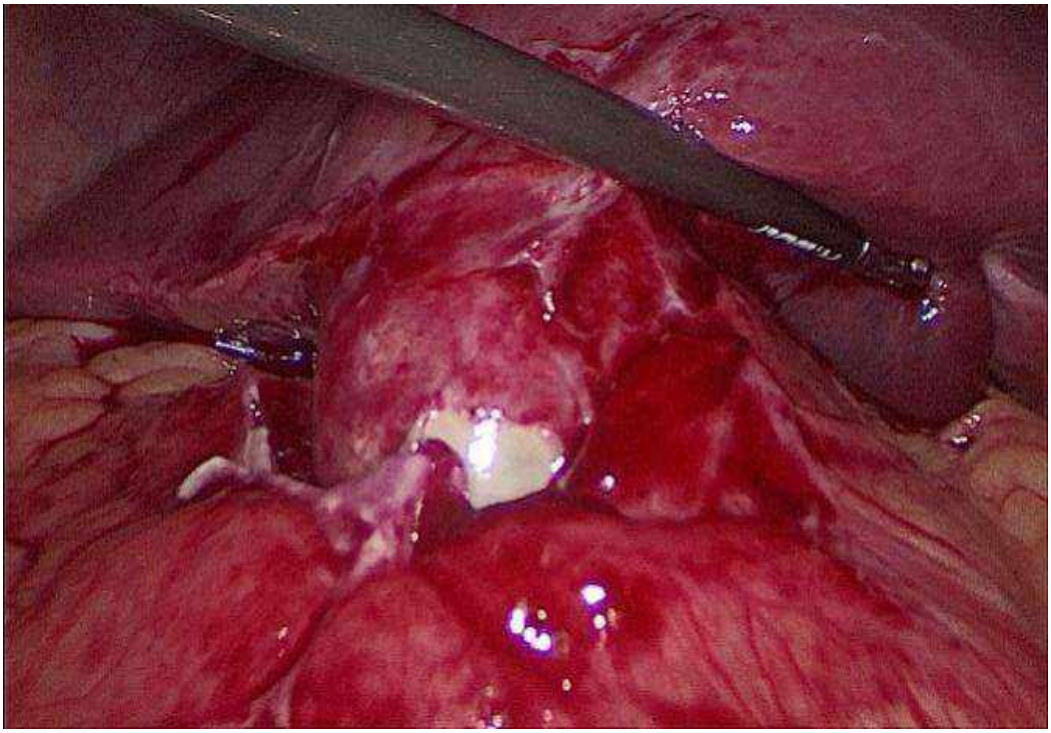
CASE 16- CBD STONES PRESENT.

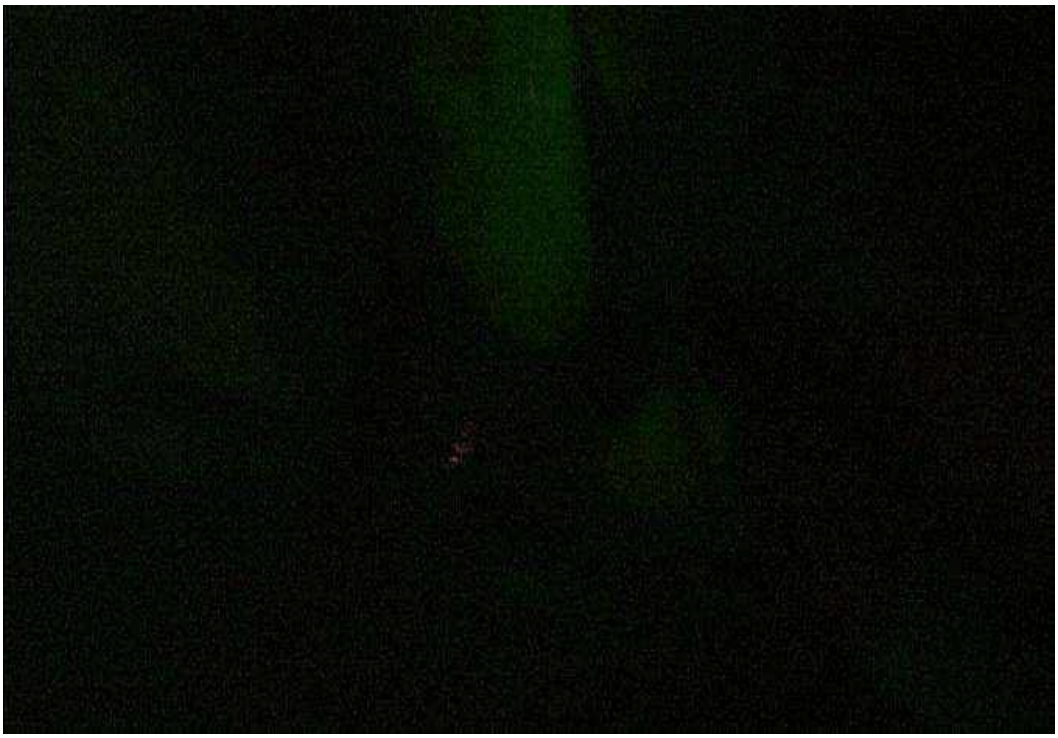


CASE 17:- IN VIEW OF DENSE ADHESIONS AND INFLAMMATORY CHANGES, BILIARY SYSTEM WAS NOT VISUALIZED ON ICG-IOC.

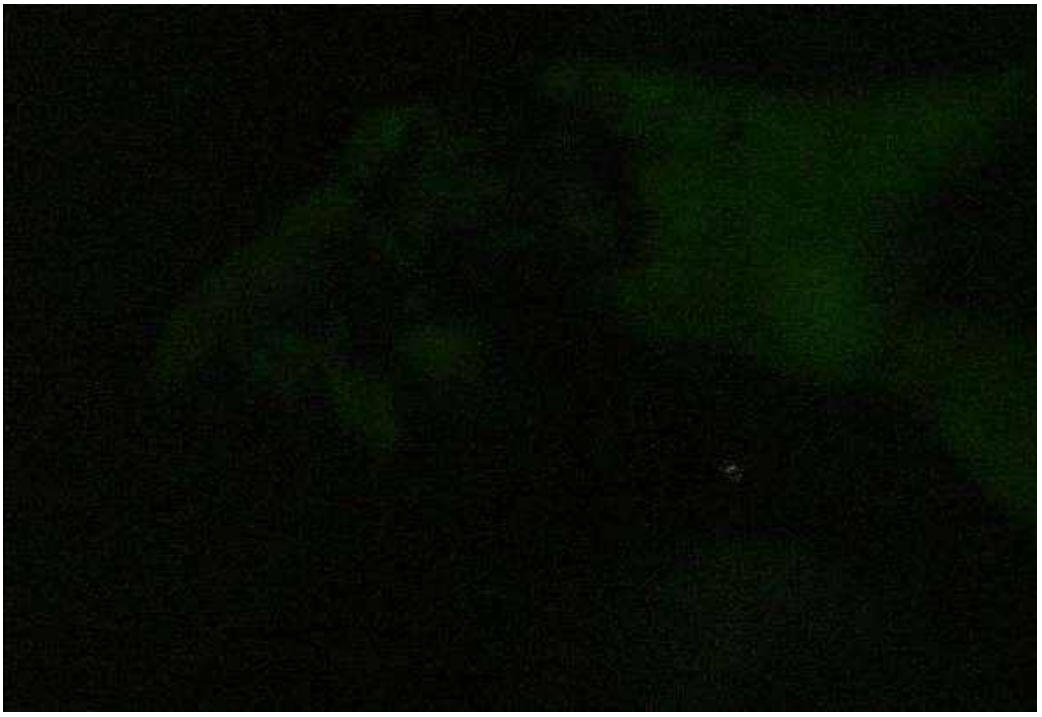


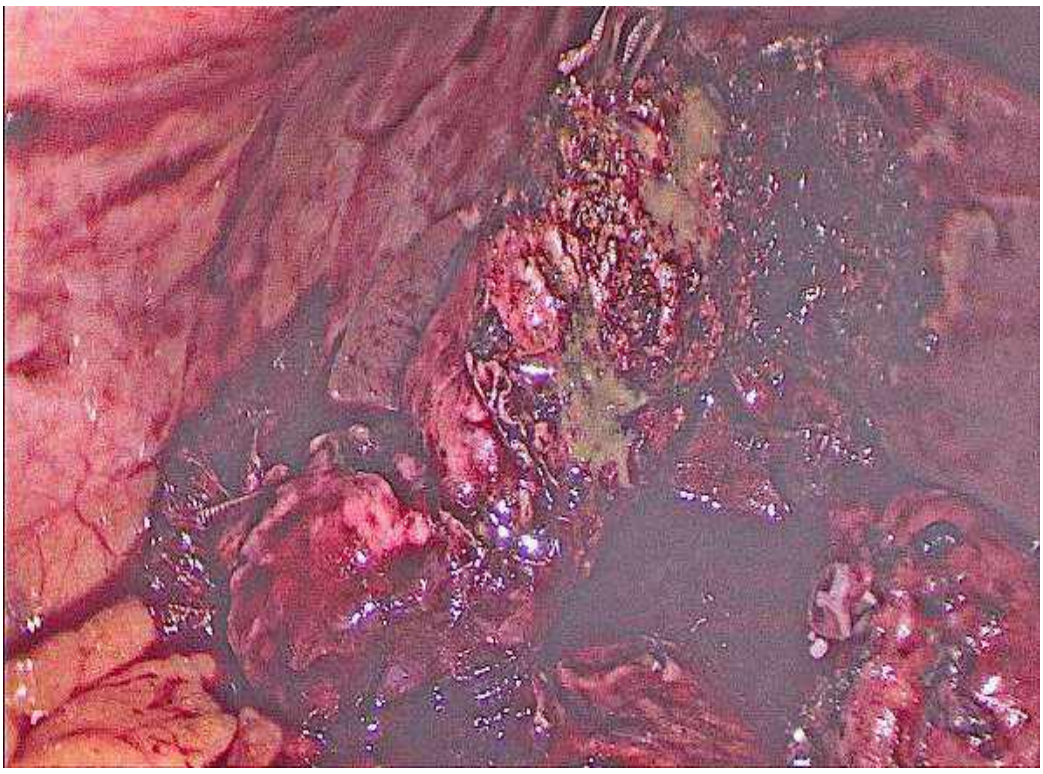
CASE 18:- IN VIEW OF INFLAMMATORY CHANGES AND CIRRHOTIC LIVER, DUCTAL ANATOMY NOT IDENTIFIED ON ICG-IOC.





CASE 19:- ACUTE GANGRENOUS CHOLECYSTITIS





CASE 20:- EMPYEMA GB

PROFORMA

PLACE: DMC&H, LUDHIANA

DATE:

TIME:

DEMOGRAPHIC DETAILS:

NAME: AGE : SEX:

MRD NO. :

DATE OF ADMISSION:

DATE OF DISCHARGE:

CLINICAL DETAILS

CHIEF COMPLAINTS:

HOPI:

1. H/O PAIN ABDOMEN : Y/N
2. H/O VOMITING/NAUSEA : Y/N
3. H/O LOSS OF APPETITE : Y/N
4. H/O FEVER : Y/N
5. H/O JAUNDICE: Y/N
6. H/O RECURRENCE : Y/N
7. H/O LOOSE STOOLS : Y/N
8. H/O CONSTIPATION : Y/N
9. H/O IODINE ALLERY : Y/N

RISK FACTORS/CO-MORBIDITIES:

1. DIABETES MELLITUS : Y/N
2. HYPERTENSION : Y/N
3. ALCOHOLISM : Y/N
4. CLD: Y/N
5. CKD : Y/N
6. THYROID DISEASE: Y/N
7. MALIGNANCY : Y/N
8. CARDIAC DISEASE : Y/N

Signature of Candidate **Signature of Supervisor**

9. ANY OTHER:

EXAMINATION :

GENERAL PHYSICAL EXAMINATION:

BP: HR: RR: SpO2:

TEMPERATURE

GCS

SYSTEMIC EXAMINATION :

PER ABDOMEN :

DIFFUSE TENDERNESS : Y/N

LOCALIZED TENDERNESS : Y/N

DISTENSION:

PALPABLE LUMP :

REBOUND TENDERNESS:

RISE OF TEMPERATURE:

INVESTIGATIONS:

1. TLC :
2. HAEMOGLOBIN :
3. TOTAL BILIRUBIN :
4. DIRECT BILIRUBIN :
5. ALP :
6. TOTAL PROTEIN :
7. ALBUMIN :
8. SERUM ELECTROLYTES(SODIUM/POTASSIUM/CHLORIDE):
9. PT/INR:
10. USG ABDOMEN: Y/N
11. IMAGING FINDINGS :
12. MRCP : Y/N
13. CT ABDOMEN : Y/N

INTRA-OP FINDINGS:

1. TECHNIQUE USED

Signature of Candidate **Signature of Supervisor**

a. NUMBER OF PORTS : 3/4

b. LOCATION OF PORTS:

i. UMBILICAL : Y/N

ii. EPIGASTRIC : Y/N

iii. RIGHT HYPOCHONDRIUM : Y/N

iv. RIGHT LUMBAR : Y/N

c. TIMING OF ADMINISTRATION:

i. 1 HOUR PRIOR TO INDUCTION : Y/N

ii. 30 MINUTES PRIOR TO INDUCTION : Y/N

iii. 15 MINUTES PRIOR TO INDUCTION : Y/N

2. ADVERSE REACTION TO ICG: Y/N

3. TIMING OF FIRST VISUALIZATION OF GALL BLADDER:

4. TIMING OF FIRST VISUALIZATION OF CYSTIC DUCT:

5. TIMING OF FIRST VISUALIZATION OF CBD :

6. CONVERSION TO OPEN PROCEDURE: Y/N

7. BLOOD LOSS IN SURGERY :

a. <500 ML : Y/N

b. >500 ML : Y/N

8. DURATION OF SURGERY :

POST-OP COMPLICATIONS:

1. HEMATOMA : Y/ N

2. CYSTIC DUCT INJURY : Y/N

3. CBD INJURY :

A. PRESENT : Y/N

B. CLASS (AS PER STRASSBERG CLASSIFICATION):

4. CYSTIC ARTERY INJURY :Y/N

Signature of Candidate **Signature of Supervisor**

S. no.	Name	Age	Sex	MRD	DOA	DOD	Hospital stay	Pain Abdomen	Nausea	Vomiting	Appeitie loss	Fever	Jaundice	Recurrence	Loose Stools	Constipation	Iodine Allergy	T2DM	HTN	Alcohol	CLD	CKD	Thyroid disease	Malignancy	Cardiac disease
1	AK	56	M	999448	14-12-2020	17-12-2020	3	Y	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
2	KD	72	F	1039240	10-03-2021	11-03-2021	1	Y	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	N	N
3	AS	18	F	1039984	04-03-2021	16-03-2021	12	Y	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	N	N	N	N	N
4	KC	56	M	6411524	27-11-2020	01-12-2020	4	Y	N	N	N	N	N	N	N	N	N	Y	N	Y	Y	N	N	N	N
5	BS	65	M	174941	07-11-2020	13-11-2020	6	Y	N	N	Y	N	N	Y	N	N	N	Y	N	N	N	N	N	N	N
6	BK	45	F	1141113	22-07-2021	27-07-2021	5	Y	Y	Y	N	T	N	N	N	N	N	T	N	N	N	N	N	N	N
7	BS	69	M	1002809	07-07-2021	19-07-2021	12	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
8	MK	39	F	1130378	04-07-2021	09-07-2021	5	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
9	SL	64	M	1138103	19-07-2021	22-07-2021	3	Y	Y	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
10	BR	55	F	576508	19-07-2021	23-07-2021	4	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
11	AK	63	M	204768	06-09-2021	09-09-2021	3	Y	Y	N	N	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N
12	SD	78	M	1176899	20-09-2021	25-09-2021	5	Y	N	Y	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
13	GK	32	F	120948	13-08-2021	16-08-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
14	IB	60	F	982582	02/11/20202	11-06-2020	4	Y	Y	Y	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N	N
15	VK	54	F	1021486	14-02-2021	18-02-2021	4	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
16	K	32	F	559925	19-03-2021	22-03-2021	3	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
17	Sk	55	F	1116507	06-06-2021	09-06-2021	3	Y	Y	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
18	VK	39	F	686762	14-02-2021	17-02-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
19	NK	38	F	993145	05-12-2020	09-12-2020	4	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20	GS	75	M	150122	05-11-2020	09-11-2020	4	Y	N	Y	N	Y	N	N	N	N	N	Y	Y	N	N	N	N	N	N
21	RK	50	F	1022017	03-12-2021	07-12-2021	4	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
22	NS	68	M	684742	18-11-2020	21-11-2020	3	Y	N	N	N	N	Y	N	N	Y	N	Y	N	N	N	N	N	N	Y
23	AK	63	F	1005669	29-10-2020	06-11-2020	6	Y	Y	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	Y
24	AK	29	F	261806	13-07-2020	17-07-2020	4	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
25	LY	42	M	990234	22-11-2020	24-11-2020	2	Y	N	N	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
26	NR	29	F	956736	19-08-2020	24-08-2020	6	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
27	RK	36	F	1164871	20-10-2021	23-10-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
28	MS	62	M	1200984	01-11-2021	15-Nov	14	Y	Y	Y	Y	N	Y	N	N	N	N	Y	Y	N	N	N	N	N	N
29	TS	51	M	1188007	08-10-2021	14-10-2021	6	Y	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	Y	N	N
30	PR	40	F	1080516	11-04-2021	14-04-2021	3	Y	Y	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
31	KL	49	M	1076419	06-04-2021	09-04-2021	3	Y	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N
32	AK	38	M	289897	18-04-2021	20-04-2021	2	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33	J	25	F	1059481	22-03-2021	25-03-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
34	AB	36	M	228738	28-05-2021	30-05-2021	2	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
35	JK	58	F	1070686	05-04-2021	09-04-2021	4	Y	N	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N
36	RC	66	M	1077141	04-04-2021	08-04-2021	4	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Other co-morbidities	BP	HR	RR	SpO2	Temperature	GCS	Diffuse tenderness	Localized tenderness	Distension	Palpable Lump	Rebound tenderness	Rise of temperature	TLC	PMN	Lymphocytes	Eosinophils	HB	TB	DB	ALP	TP	Alb	S. Sodium	S. Potassium	S. Chloride
N	110/70	76	20	98	98.6	15	Y	N	N	N	N	N	9.8	64.3	25.9	2	13.3	0.55	0.11	103	7.6	3.92	139	4.37	106
N	120/70	75	22	98	98.7	15	N	Y	N	N	N	N	6.7	52.3	25.5	3.4	12.6	0.42	0.21	121	7.7	3.8	140	4.2	108
MILD ACIUTE PANCREATITIS	120/70	70	24	98	98.6	15/15	Y	N	Y	Y	N	N	17.1	89	20	2.6	10.9	1.41	0.77	210	7.1	4.01	137	4.8	102
N	110/70	70	22	98	98.4	15/15	Y	N	N	N	N	N	8.4	61.1	28.7	3	13.2	0.55	0.38	101	6.7	4.07	142	4.45	109
N	120/70	80	24	98	99	15/15	Y	N	Y	Y	N	N	11.2	67	18	4	11.8	0.76	0.3	121	6.7	4.5	130	4.5	108
N	120/80	104	20	97	98.6	E4V5M6	Y	N	Y	N	N	N	11.8	79.9	12.2	3.4	10	0.28	0.115	167	7.1	3.5	141	4.6	105
PARKINSON'S	120/80	74	20	98	AFEBRILE	15/15	N	N	N	N	N	N	9	74.6	13.9	2.42	12.8	0.65	0.28	653	7.2	3.28	139	3.03	103
N	120/70	80	20	97	98.4	15/15	N	Y	N	Y	N	N	6.4	63.1	23.3	1.89	7.1	0.6	0.11	104	7.4	4.12	138	3.87	104
N	120'/70	60	18	97	AFEBRILE	15/15	N	Y	N	N	N	N	7.4	54.2	28.1	4.2	11.5	1.34	0.36	68	7.5	4.19	139	4.23	109
SOLITARY KIDNEY,PTB	110/70	70	17	98	98.6	15	N	N	N	N	N	N	7.1	71.2	11.7	3.4	11.8	0.56	0.11	147	6.6	4.02	140	4.4	106
CVA	120/70	80	20	98	98.6	15/15	N	N	N	N	N	N	8	64.1	23.4	2.3	14.2	0.54	0.1	55	7.2	4.01	136	4.46	100
BLADDER OUTLET OBSTRUCTION	120/70	90	20	97	98.7	15/15	N	Y	N	N	N	N	15.9	30.9	63.3	4.8	13.8	1.39	0.39	86	6.7	4	139	4.37	109
N	120/70	80	20	98	98.7	15/15	N	N	N	N	N	N	10	70	19.8	2.3	13	0.6	0.1	80	6.5	3.4	139	4.3	106
N	110/70	70	18	98	98.6	15	N	N	N	N	N	N	16	82.3	10.5	2.3	11	0.56	0.23	102	7.1	4.3	140	4.2	107
N	130/70	90	20	98	98.6	15/15	N	Y	N	N	N	N	7	54.5	24.5	3.4	12.3	0.6	0.2	109	7.4	3.7	139	4.34	108
N	120/70	80	20	98	98.6	15	N	N	N	N	N	N	11.8	70.5	22.9	5.6	11.7	0.36	0.06	183	6.2	4.78	137	4.48	104
N	140/70	90	20	98	98.7	15	Y	Y	N	N	N	N	7	57.3	30.2	1.3	9.8	0.83	0.18	101	7.1	4.26	137	4.2	109
N	130/70	72	20	99	98.6	15	N	N	N	N	N	N	6.4	56.4	24.4	3.5	10.9	0.98	0.23	115	7.5	3.9	140	3.98	110
N	120/70	90	22	98	98.6	15	N	N	N	N	N	N	8.1	74.4	18.1	5	12.2	0.44	0.18	106	7.9	4.56	142	4.5	103
N	150/80	100	20	99	98.6	15	Y	Y	N	Y	Y	Y	16.9	86.9	31.3	6.7	12	0.41	0.2	213	6.4	3.79	143	4.68	105
N	120/70	86	20	98	98.4	15	N	N	N	N	N	N	8.7	59.4	30.7	5.9	11.7	0.37	0.05	12.9	7.6	4.07	137	4.31	102
N	100/60	60	22	96	98.8	15	N	N	N	N	N	N	4.6	62.8	22.2	10.1	13.1	0.69	0.26	51	6.9	4.28	140	4.73	10.5
N	110/70	58	22	97	98.6	15	N	Y	Y	N	Y	N	15.7	84.3	7.1	7.9	11.7	1.28	0.74	106	6.6	3.13	138	3.95	97
N	120/70	74	20	98	98.6	15	N	N	N	N	N	N	5.9	62.1	27.4	7.8	12.2	0.83	0.23	132	7.9	4.48	141	4.97	104
N	120/70	100	20	98	98.6	15	Y	N	Y	N	Y	Y	21	89.4	6.8	4.2	12.1	1.1	0.36	140	7.2	4.2	137	4.3	108
N	120/70	80	20	98	98.6	15	N	Y	Y	Y	N	N	13.1	72.4	16.4	10.3	10.7	0.72	0.19	83	7	4.09	141	4.29	103
N	120/70	76	22	98	98.6	15	N	Y	N	N	Y	N	6.2	53.3	35.8	8.2	8.3	0.54	0.21	79	7.1	4.6	139	3.95	104
ACUTE MILD PANCREATITIS	110/70	76	20	98	98.8	15	Y	N	Y	N	N	N	12	78.5	12.3	7.7	10.7	2.56	2.21	484	5.9	2.93	133	4.17	100
PITUITARY MACROADENOMA	120/70	76	20	98	98.6	15	N	N	N	N	N	N	5.9	62	28	8.2	9.8	0.39	0.06	151	6.8	4.1	138	5.31	106
N	120/70	90	20	98	98.6	15	N	Y	N	N	N	N	6.3	60.8	25.7	10.6	9.1	0.68	0.15	120	6.2	3.57	139	4.02	108
N	130/70	90	20	97	98.6	15	N	N	N	N	N	N	8.3	54.5	34	10.1	12.7	0.37	0.18	88	6.9	4.16	141	3.87	104
N	120/70	70	20	98	98.6	15	N	Y	N	N	Y	N	9.1	70.4	20.6	4.8	13.7	0.29	0.17	85	6.6	4.35	147	4.03	110
N	130/70	80	20	98	98.6	15	N	N	N	N	N	N	6.5	67.4	19.7	2.4	17.3	0.31	0.2	63	6.9	3.95	136	3.82	107
N	110/70	72	18	98	98.6	15	N	Y	N	N	N	N	6.8	53.6	32.5	5.8	13.8	0.49	0.1	88	7.1	4.44	139	4.58	102
N	120/70	82	17	98	98.6	15	N	N	N	N	N	N	11.3	77.5	10.7	1.4	12.4	0.8	0.26	83	5.5	3.01	131	3.54	97
N	110/70	76	20	98	98.76	15	N	N	N	N	N	N	9.7	84.3	9.4	0.6	11.4	1.06	0.55	93	5.2	3.19	129	4.21	97

INR	USG	Imaging Findings	MRCP	CT	Number of ports	Umbilical port	Epigastric Port	Right hypochondirum port	Right lumbar port	Timing 1 hr	Time 30 mins	Time 15 mins	Reaction to ICG	gb visualization	Cystic duct visualization	CBD Visualization	open convert	Blood loss <500	Blood loss >500	Duration of Surgery (hours)	Hematoma	Cystic Duct Injury	CBD Injury	Class of CBD Injury	Cystic Artery Injury
1.14	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	N	Y	N	N	20	30	N	Y	N	1	N	N	N	N	N
1.16	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	N	1	N	N	25	30	N	Y	N	1	N	N	N	N	N
1.39	Y	GALL STONES WITH ACUTE PANCREATITIS WITH	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	20	20	N	Y	N	60	N	N	N	N	N
0.95	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	35	35	35	N	Y	N	50	N	N	N	N	N
0.89	Y	ACUTE CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	40	30	N	Y	N	60	N	N	N	N	N
1.17	Y	ACUTE CALCULOUS CHOLECYSTITIS	N	Y	4	Y	Y	Y	Y	N	N	Y	N	10MIN	35MIN	Y	N	Y	N	60	N	N	N	N	N
1.03	N	GALL STONES WITH CBD	Y	N	4	Y	Y	Y	Y	N	Y	N	N	25MIN	N/A	20	N	Y	N	120	N	N	N	N	N
1.15	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	15MIN	20MIN	20	N	Y	N	35MIN	N	N	N	N	N
1.11	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	N	Y	N	15MIN	20MIN	20	N	Y	N	30MIN	N	N	N	N	N
1.04	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	N	Y	N	20MIN	30MIN	20	N	Y	N	40MIN	N	N	N	N	N
10.9/1	Y	GALL STONES WITH SLUDGE]	N	N	4	Y	Y	Y	Y	N	N	Y	N	20	20	20	N	Y	N	60	N	N	N	N	N
11.8/1.0	Y	ACUTE CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	35	20	N	Y	N	60	Y	N	N	N	N
11/1.09	Y	ACUTE CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	Y	45	45	35	N	Y	N	60	N	N	N	N	N
1.23	Y	ACUTE GANGRENOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N/A	N	N	Y	N	90	N	N	N	N	N
1.4	N	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	70	N	N	N	N	N
1.25	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	20	20	15	N	Y	N	50	N	N	N	N	N
0.98	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	45	35	30	N	Y	N	65	N	N	N	N	N
0.9	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	25	25	20	N	Y	N	45	N	N	N	N	N
1.05	Y	GALL STONES	N	Y	4	Y	Y	Y	Y	N	Y	N	N	35	35	25	N	Y	N	45	N	N	N	N	N
1.1	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	45	N	N	N	N	N
1	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	35	25	20	N	Y	N	60	N	N	N	N	N
12	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	30	25	N	Y	N	90	N	N	N	N	N
1.15	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	30	25	N	Y	N	60	N	N	N	N	N
1.05	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	Y	N	Y	N	30	20	15	N	Y	N	40	N	N	N	N	N
1.2	Y	GALL STONES	N	N	4	Y	Y	Y	Y	Y	N	N	N	40	30	25	N	Y	N	90	N	N	N	N	N
1.18	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	25	20	N	Y	N	60	N	N	N	N	N
1	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	25	35	30	N	Y	N	60	N	N	N	N	N
1.39	Y	GALL STONES WITH ACUTE PANCREATITIS WITH	Y	N	4	Y	Y	Y	Y	N	Y	N	N	45	50	45	Y	Y	Y	120	N	N	Y	E2	N
0.98	Y	GALL STONES WITH SLUDGE .	N	N	4	Y	Y	Y	Y	N	Y	N	N	25	20	15	N	N	N	60	N	N	N	N	N
1.1	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	20	20	15	N	Y	N	45	N	N	N	N	N
0.95	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	25	20	N	Y	N	60	N	N	N	N	N
0.95	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	20	15	N	Y	N	45	N	N	N	N	N
1.12	Y	GALL STONES	N	Y	4	Y	Y	Y	Y	N	Y	N	N	40	40	30	N	Y	N	65	N	N	N	N	N
1.06	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	15	N	Y	N	45	N	N	N	N	N
1.26	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	Y	4	Y	Y	Y	Y	N	Y	N	Y	45	45	35	N	Y	N	70	N	N	N	N	N
1.23	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	45	45	40	N	Y	N	60	N	N	N	N	N

S. no.	Name	Age	Sex	MRD	DOA	DOD	Hospital stay	Pain Abdomen	Nausea	Vomiting	Appeitie loss	Fever	Jaundice	Recurrence	Loose Stools	Constipation	Iodine Allergy	T2DM	HTN	Alcohol	CLD	CKD	Thyroid disease	Malignancy	Cardiac disease
37	BS	38	M	1030275	27-09-2021	30-09-2021	3	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
38	RM	69	F		29-09-2021	01-10-2021	3	Y	N	N	Y	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N
39	PL	50	F	102131	01-02-2021	05-02-2021	4	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40	PG	54	F	199070	24-03-2021	27-03-2021	3	Y	Y	Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N
41	JM	55	F	867832	18-03-2021	21-03-2021	3	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
42	MB	60	F	1029132	02-03-2021	05-03-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
43	S	69	M	1054971	17-03-2021	23-03-2021	6	Y	Y	Y	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N
44	RJ	46	F	1031046	09-03-2021	13-03-2021	4	Y	Y	Y	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N
45	RL	42	M	1020171	31-01-2021	03-02-2021	4	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
46	KT	18	F	948991	02-08-2020	05-08-2020	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
47	SK	30	F	1194994	26-10-2021	02-11-2021	7	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
48	MG	36	F	1181589	28-09-2021	02-10-2021	4	Y	N	N	N	N	N	N	N	N	N	Y	Y	N	N	N	Y	N	N
49	A	37	F	29426	25-11-2021	28-11-2021	3	Y	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N
50	A	28	F	1192493	17-10-2021	22-10-2021	5	Y	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N
51	RR	36	F	117842	22-09-2021	25-09-2021	3	Y	N	N	N	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N
52	PD	54	F	1174184	15-09-2021	18-09-2021	3	Y	N	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	Y
53	RA	58	F	1048208	12-08-2021	15-08-2021	3	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
54	KK	38	F	514466	31-12-2019	02-01-2020	3	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
55	SD	60	F	836115	20-12-2019	23-12-2019	3	Y	N	N	N	Y	N	Y	N	N	N	N	N	N	N	N	N	N	N
56	PJ	84	M	1182639	04-10-2021	07-10-2021	3	Y	N	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	Y
57	Sk	70	F	1152759	24-09-2021	29-09-2021	5	Y	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
58	MK	31	F	1091741	12-06-2021	13-06-2021	1	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
59	PR	45	F	800369	20-06-2021	24-06-2021	4	Y	N	N	N	Y	N	N	N	N	N	Y	N	N	N	N	N	N	N
60	UR	66	F	932583	21-06-2021	23-06-2021	2	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
61	GS	51	M	944522	22-11-2021	25-11-2021	3	Y	N	N	N	N	N	Y	N	N	N	Y	Y	N	N	N	N	N	Y
62	VK	65	F	1210152	19-11-2021	24-11-2021	5	Y	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	N	N
63	MD	27	F	1192716	18-10-2021	22-10-2021	4	Y	N	Y	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N
64	RD	32	F	1192871	18-10-2021	21-10-2021	3	N	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
65	S	50	M	1022076	25-10-2021	30-10-2021	5	Y	N	N	N	N	N	N	N	N	N	N	Y	N	Y	N	N	N	N
66	YS	22	M	977214	27-10-2020	29-10-2020	2	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
67	PS	33	F	1021486	03-02-2021	08-02-2021	5	Y	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N
68	J	18	F	977214	18-10-2020	20-10-2020	2	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
69	AS	40	M	971460	27-10-2020	30-10-2020	3	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
70	PK	41	F	980013	26-10-2020	28-10-2020	2	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
71	SL	62	F	900118	26-10-2020	02-11-2020	6	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Other co-morbidities	BP	HR	RR	SpO2	Temperature	GCS	Diffuse tenderness	Localized tenderness	Distension	Palpable Lump	Rebound tenderness	Rise of temperature	TLC	PMN	Lymphocytes	Eosinophils	HB	TB	DB	ALP	TP	Alb	S. Sodium	S. Potassium	S. Chloride
N	110/70	76	20	98	98.7	15	N	N	N	N	N	N	5.5	56	32.8	7.9	13.9	0.65	0.1	62	7	4.68	141	4.16	106
N	120/70	86	19	97	98.6	15	N	N	N	N	N	N	7.2	59.4	29.1	7.7	12	0.3	0.13	106	7.3	4.05	140	4.62	105
N	110/70	84	22	98	98.5	15	N	N	N	N	N	N	6.6	55.7	28	2.4	11.4	0.56	0.34	111	7.8	4.3	141	4.67	101
N	110/60	74	20	98	98.6	15	N	Y	N	N	N	N	6.8	57.7	33.2	6.6	13.1	0.54	0.09	101	7.8	4.22	138	4.1	104
N	120/70	86	20	98	98.6	15	N	N	N	N	N	N	10.2	52.7	31.3	6.7	12	0.41	0.2	213	6.4	3.79	143	4.68	105
N	100/60	58	20	98	98.6	15	N	N	Y	N	N	N	5.5	58	27.8	8	9.1	0.3	0.16	75	7	4.09	143	4.4	107
N	110/70	60	16	98	98.6	15	N	Y	N	N	N	N	9.2	81.4	10.8	7.5	11.8	0.57	0.34	65	6.3	3.48	140	3.92	101
N	100/60	64	18	98	98.8	15	N	Y	N	N	N	N	9.2	59.5	31.1	6.2	12.8	0.6	0.14	72	7.5	4.66	138	4.3	104
N	110/80	82	17	98	98.7	15	N	Y	N	N	N	N	12.2	81.6	10.5	7.5	12.1	0.41	0.21	291	7	3.99	137	4.2	100
N	140/70	95	20	98	98.6	15	Y	N	N	N	N	N	13.3	68.7	21.7	5.6	10.8	0.31	0.1	151	7.4	4.41	142	5.1	105
N	130/70	90	20	98	98.6	15	Y	N	Y	N	N	N	15	88	10.6	5.2	10.6	0.78	0.59	302	6.8	3.64	138	4.78	103
N	130/70	90	24	99	98.8	15	N	N	N	N	N	N	6	75.2	11.7	10.1	11.4	0.44	0.09	97	7.6	4.19	138	4.43	101
N	120/70	95	22	98	98.6	15	N	N	N	N	N	N	6.8	60.4	26.9	8.8	11.3	0.35	0.09	104	7.2	4.5	140	4.3	103
N	130/70	98	20	98	98.8	15	N	N	N	N	N	N	8.1	48.3	38.8	8.4	11.5	0.7	0.13	101	6.8	3.95	140	4.3	109
N	130/70	98	20	98	98.6	15	N	Y	N	N	N	N	11.6	71.6	20.2	7.1	11.7	0.72	0.14	111	7.7	4.29	138	4.38	102
N	140/80	104	20	98	99	15	Y	N	N	Y	N	N	22	83.5	7.2	9.1	10.7	1.13	0.48	119	6.7	3.47	135	3.86	102
N	130/70	90	20	98	98.6	15	N	N	N	N	N	N	6.7	59.2	29	6.6	11	0.38	0.07	79	6.7	3.88	139	4.02	106
N	110/70	70	20	98	98.6	15	N	N	N	N	N	N	6	71.5	19.2	1.3	12.8	0.81	0.21	72	7.9	4.51	138	4.04	102
F/U C/O BILIARY	110/70	90	18	98	98.7	15	N	N	Y	N	N	N	5.6	52.3	33.4	3.9	10.5	0.51	0.11	122	7.2	3.12	140	3.68	102
N	110/70	70	20	98	98.6	15	N	N	N	N	N	N	8.3	61.4	25.6	2	15.7	1.73	0.27	133	6.6	4.25	139	3.66	101
N	120/70	70	16	98	98.6	15	N	N	Y	N	N	N	4.3	55.3	35.2	2.8	11.6	0.24	0.12	123	6.7	3.84	140	4.52	106
N	120/70	70	20	98	98.6	15	N	N	N	N	N	N	6.7	49.7	33.7	8.5	13.1	0.4	0.23	88	6.7	4.35	140	4.62	107
BRONCHIAL ASTHMA	140/70	90	20	98	98.7	15	N	N	N	N	N	Y	8.2	70.2	16.7	2.32	9.9	0.36	0.15	194	6.9	3.38	140	3.96	101
N	110/70	98	20	98	98.6	15	Y	N	Y	N	N	Y	17.3	86.2	4.4	0	10.9	1.32	0.57	126	6.5	3.64	130	4.03	97
N	130/80	60	18	98	98.6	15	N	N	Y	N	N	N	6	65.4	23.2	0.9	13	0.51	0.2	109	8.2	4.7	141	4.71	102
N	120/70	80	20	98	98.6	15	N	Y	N	Y	Y	N	4	51.5	37	2.7	11.5	0.7	0.17	93	7.1	3.63	140	3.78	106
N	110/70	80	20	98	98.6	15	N	Y	N	Y	Y	Y	4.3	52.3	33.8	1.5	8.6	0.39	0.17	109	6.1	3.43	140	3.64	102
N	110/70	70	16	98	98.6	15	N	N	N	N	N	N	6	55.9	34.6	2	11.4	1.21	0.46	75	6.9	4.55	141	4.22	106
N	100/70	60	20	98	98.6	15	N	N	Y	N	N	N	7.7	87.2	9.1	0.1	12.5	0.82	0.43	262	7.3	3.79	137	4.37	108
F/U C/O BILIARY PANCREATITIS	110/70	80	20	98	98.6	15	N	N	N	N	N	N	8.4	56.7	24.6	4.2	11	0.53	0.2	130	7	4.1	140	4.2	101
N	120/70	76	18	98	98.6	15	N	N	N	N	N	N	6.7	45.5	24.5	3.4	12.5	0.7	0.2	129	7.2	3.9	138	4.1	100
N	130/80	90	20	98	98.7	15	N	N	N	N	N	N	7	53.2	25.5	4	13.6	0.45	0.1	120	7	4	139	4.1	102
RHEUMATOID	110/80	77	19	98	98.5	15	N	N	Y	N	N	N	8.6	54.4	20.6	2.2	12.6	0.44	0.12	139	6.9	3.6	139	4.2	100
N	120/70	70	20	98	98.7	15	N	N	N	N	N	N	4.5	44.5	23	2.3	12	0.45	0.12	140	7.5	3.9	140	3.99	103
N	130/70	80	19	98	98.6	15	N	N	N	N	N	N	5.6	44	34.5	2.1	12	0.58	0.08	137	7.1	3.5	139	4.5	100

INR	USG	Imaging Findings	MRCP	CT	Number of ports	Umbilical port	Epigastric Port	Right hypochondirum port	Right lumbar port	Timing 1 hr	Time 30 mins	Time 15 mins	Reaction to ICG	gb visualization	Cystic duct visualization	CBD Visualization	open convert	Blood loss <500	Blood loss >500	Duration of Surgery (hours)	Hematoma	Cystic Duct Injury	CBD Injury	Class of CBD Injury	Cystic Artery Injury
0.96	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	60	N	N	N	N	N
1.16	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	N	Y	N	N	32	32	25	N	Y	N	60	N	N	N	N	N
1.1	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	55	N	N	N	N	N
1.1	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	31	28	25	N	Y	N	60	N	N	N	N	N
1.1	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	45	N	N	N	N	N
0.99	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	36	32	25	N	Y	N	65	N	N	N	N	N
1.2	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	38	38	30	N	Y	N	55	N	N	N	N	N
1.24	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	24	N	Y	N	50	N	N	N	N	N
1.13	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	25	25	15	N	Y	N	40	N	N	N	N	N
1.03	Y	ACUTE GANGRENOUS CHOLECYSTITIS WITH	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	50	N	N	N	N	N
1.24	Y	EMPYEMA GB	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	45	N	N	N	N	N
1.05	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	35	35	30	N	Y	N	50	N	N	N	N	N
0.97	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	20	N	Y	N	45	N	N	N	N	N
1.03	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	Y	N	N	45	45	30	N	Y	N	65	N	N	N	N	N
1.1	Y	GALL STONES	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	40	25	N	Y	N	50	N	N	N	N	N
1.28	Y	ACUTE CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	70	N	N	N	N	N
1.07	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	50	N	N	N	N	N
1.17	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	20	N	Y	N	40	N	N	N	N	N
1.19	Y	CHRONIC CALCULOUS	N	N	4	Y	Y	Y	Y	N	Y	N	N	50	50	50	N	Y	N	70	N	N	N	N	N
1.09	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	30	N	Y	N	50	N	N	N	N	N
1.08	Y	GALL STONES WITH SLUDGE	N	N	4	Y	Y	Y	Y	N	Y	N	N	50	50	45	N	Y	N	60	N	N	N	N	N
1.07	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	20	N	Y	N	45	N	N	N	N	N
1.36	Y	MUCOCELE GB	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	70	N	N	N	N	N
1.34	Y	ACUTE GANGRENOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	65	N	N	N	N	N
0.98	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	25	25	15	N	Y	N	35	N	N	N	N	N
1.03	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	N	Y	N	N	N	40	35	N	Y	N	60	N	N	N	N	N
1.34	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	45	35	N	Y	N	60	N	N	N	N	N
1.15	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	45	N	N	N	N	N
1.26	Y	MUCOCELE GB	Y	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	60	N	N	N	N	N
1.1	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	45	40	N	Y	N	60	N	N	N	N	N
1.23	Y	GALL STONES WITH CBD STONES	Y	N	4	Y	Y	Y	Y	N	Y	N	N	40	40	30	N	Y	N	60	N	N	N	N	N
1.2	Y	CHRONIC CALCULOUS	N	N	4	Y	Y	Y	Y	N	Y	N	N	30	30	25	N	Y	N	50	N	N	N	N	N
0.96	Y	CHRONIC CALCULOUS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	40	40	N	Y	N	55	N	N	N	N	N
0.89	Y	CHRONIC CALCULOUS CHOLECYSTITIS	N	N	4	Y	Y	Y	Y	N	Y	N	N	40	40	40	N	Y	N	50	N	N	N	N	N
0.99	Y	MUCOCELE GB	N	N	4	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	Y	N	80	N	N	N	N	N

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50

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Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of **Dr. Anubhavv Gupta,** a student of your college for **MS General Surgery** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Evaluation of the role indocyanine green in laparoscopic cholecystectomy

Supervisor
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Prof. & Head,
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Dr. Sanjeev K. Singla
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The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

SPSingh
Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

1. ***If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.***
2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

M.S.

in

Surgery

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES
FARIDKOT

JUNE, 2020

Dr Anubhavv Gupta

DEPARTMENT OF SURGERY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY"** exist in the Department of Surgery, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate himself under our supervision and guidance.

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5	TITLE OF THE TOPIC	EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY.

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

The first laparoscopic cholecystectomy(LC) was performed in India by Dr. T.E. Udwadia, at JJ Hospital, Mumbai in 1990 and is one of the most common operations in the surgical field, with more than 60,000 operations performed in Japan and approximately 750,000 in the United States every year.[1,2]

Described for the first time in 1983, the most common indication for laparoscopic cholecystectomy is symptomatic gall stone disease. Other indications include cholecystitis(acute/chronic/acalculous), biliary dyskinesia or a gall bladder mass/polyp. It significantly reduced the operating time as compared to open surgical cholecystectomy. It also has the added advantage of shorter duration of hospital stay.

In its initial stages, laparoscopic cholecystectomy was used only for chronic cholecystitis, then it began to be used for cases like empyema gall bladder, cholecystitis in a patient with frozen calot's triangle, a history of previous abdominal surgery or in a patient with mirizzi syndrome, which were considered to be difficult lap. Cholecystectomies.[3,4,5]

The gallbladder situated on the inferior aspect of the liver bed, more specifically under the junction of liver segments 4b and 5. The gall bladder can be up to 10 cm in length and physiologically can hold up to 50 cc of fluid (bile). A line from the gallbladder to the inferior vena cava separates the liver into right and left lobes. There are four anatomical sections to the gallbladder: fundus, body, infundibulum, and neck. There is great variation in the biliary ductal anatomy.

The most dreaded complication during a cholecystectomy still remains to be injury to the common bile duct, the incidence of which varies from 0.1-0.2% in open cholecystectomies and has a still higher incidence of about 0.4-0.6% during lap. Cholecystectomies.[6]

To work around this and to reduce the incidence of injury to the common bile duct during the procedure, intra-operative visualization of the biliary tree was introduced using a cholangiogram.

Intra-operative cholangiography using either fluoroscopy or near infrared imaging is a technique that is used to visualize the biliary tree by instillation of a contrast agent which delineated the biliary tree. This imaging method can be used either routinely as recommended by the SAGES guidelines or selectively based on pre or peri-operative indications. [7]

Table 22.1. Indications of selective intraoperative cholangiography

Preoperative indications	History	• Acholic stools • Icterus • Pancreatitis • Cholangitis
	Ultrasound	• Dilated common bile duct
	Biochemical	• Elevated bilirubin • Elevated alkaline phosphatase
	Anatomy which precludes ERCP	• Previous surgery—RYGB • Duodenal diverticulum
Intraoperative indications	• Dilated bile duct • Stones or sludge in cystic or bile duct • Unclear anatomy • Suspected bile duct injury	• Cystic duct >5 mm • Common duct >10 mm

Intra-operative Cholangiography is most commonly used during elective procedures to assess choledocholithiasis but can also be used in cases of biliary tract tumors and hepatic resection. Clinically silent choledocholithiasis occurs in about 1 in 25 cases of biliary colic. This method of intra-op cholangiography has a false positive rate of about 4%. Ideally, IOC should be performed prior to cutting the cystic duct. [8]

Intraoperative fluorescent imaging with indocyanine green (ICG) has been employed for confirming the patency of vascular reconstruction surgery, liver transplantation, anastomosis of the gastrointestinal tract, brain aneurysms, identification of sentinel lymph node navigation, and hepatocellular carcinoma detection.[2]

ICG is a water soluble tricarbocyanine molecule that is almost completely protein bound following intravenous injection. Following intravenous injection, it rapidly and completely binds to albumin and is selectively taken up by hepatocytes and excreted into the bile. ICG is

metabolized by the liver and excreted in bile. The angiographic feature of ICG is based on its fluorescent character in the near-infrared range between 790 and 805 nm, which can be detected by specialized infrared video cameras. The fact that ICG is metabolized in the liver and excreted via bile makes it an excellent medium for biliary tree imaging.[9]

Indocyanine green has been developed as a new method for performing intra-operative cholangiography. This helps to delineate difficult anatomy of the biliary tract, identify choledocholithiasis or guide biliary reconstruction. Indications for the selective use of cholangiography include pain on the day of operation, abnormal hepatic function panel, anomalous or confusing biliary anatomy, and alteration in anatomy that precludes the ability to perform ERCP after cholecystectomy, such as Roux-en-Y gastric bypass, dilated biliary tree, or any preoperative suspicion of choledocholithiasis.

The surgery has a rate of conversion to open of about 2-5% when used without indocyanine green, which is increased to 10-15 % in cases of emergency cholecystectomy for acute cholecystitis.[10]

The methods of using ICG for intra-operative cholangiography include either direct injection into the biliary tree via the cystic duct or any other part of the biliary tree or via an intra-venous infusion 1 hour prior to surgery.[11]

The on table approach with direct injection into the biliary tree is done by applying a clip at the junction of the cystic duct with the gall bladder after milking any stone out of the cystic duct into the gall bladder, so as to prevent slippage of stone into the CBD. Then an anterolateral ductotomy is performed, through which a 4 or 5 Fr cholangiocatheter is inserted into the cystic duct, grasped using an Olsen cholangiogram clamp and after checking patency of the catheter by pushing in Normal saline, about 10 to 20 ml of water soluble contrast in injected into the biliary tree.[12]

The shortcomings associated with IOC may include increased ductal complications like stricture formation and pancreatitis and increased procedure time in inexperienced hands. Critics to this on table

procedure also claim that this procedure be used only in cases where the critical view of safety is not achieved.

The second method involves injection of a standard dose of 0.05 mg/kg of the contrast agent several hours prior to surgery as pre-operative preparation which then gets bound to albumin and is secreted into bile which can then be visualized using near infrared imaging technique.

6.2 REVIEW OF LITERATURE

Laparoscopic Cholecystectomy is one of the most commonly performed laparoscopic procedures performed worldwide and though may seem like an easy procedure, can have a variety of serious complications. One of which would be injury to the common bile duct due to misidentification of the duct. Prevention of such injuries by careful dissection, accurate knowledge of anatomy and appropriate precautionary measures is very important. Most of these injuries are not identified at the time of surgery. If detected at operation or within 48 hours of surgery, the surgeon should proceed with repair of these injuries.[6]

During IOC, the fluoroscopic images should be assessed for length of the cystic duct and its junction with the CBD, diameter of the CBD, any luminal filling defects within the CBD, free flow of contrast into the duodenum and anatomy of the intrahepatic biliary tree.[12]

In a study by Stewart and law, only 17 % of injuries repaired by the primary surgeon, were successful. Considering this, in case an injury has occurred, only an experienced surgeon should proceed with repair of these injuries.[13]

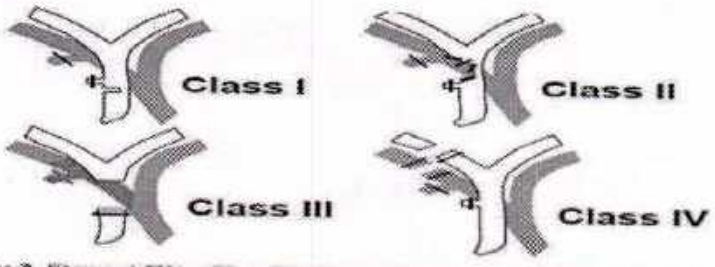
Appropriate steps to prevent injury, include careful dissection around the calot's triangle, following the critical view of safety technique introduced by Strasberg in 1995.[14,15] The SAGES expert Delphi consensus has deemed the critical view of safety to be the most critical factor for overall safety during laparoscopic cholecystectomy.

Various classifications have been provided for CBD injuries during laparoscopic cholecystectomy, based on their relations to the cystic duct and vascular lesions around. The most commonly used classifications used is the Stewart-Way classification:

Class I injuries involve an incision (i.e., an incomplete transection) of the CBD and typically occur when the CBD is mistaken for a cystic duct. Class II injuries represent lateral damage to the common hepatic duct. Class III injuries are the most common and represent a CBD mistaken for a cystic duct; these are not immediately recognized

intraoperatively. Finally, class IV injuries occur when a right hepatic duct is mistaken for a cystic duct.[8,16]

- **Class I** CBD mistaken for cystic duct, but error recognized before CBD is divided.
- **Class II** Damage to CHD from clips or cautery placed on duct. Often occurs where visibility is limited due to inflammation or bleeding.
- **Class III** Most common (60%), CBD mistaken for cystic duct. Common duct is transected and variable portion that includes junction of cystic and common duct is excised .
- **Class IV** Damage to right hepatic duct , either because this structure is mistaken for cystic duct, or injured during dissection.



re 2. Stewart-Way Classification of Laparoscopic Bile Duct Injuries

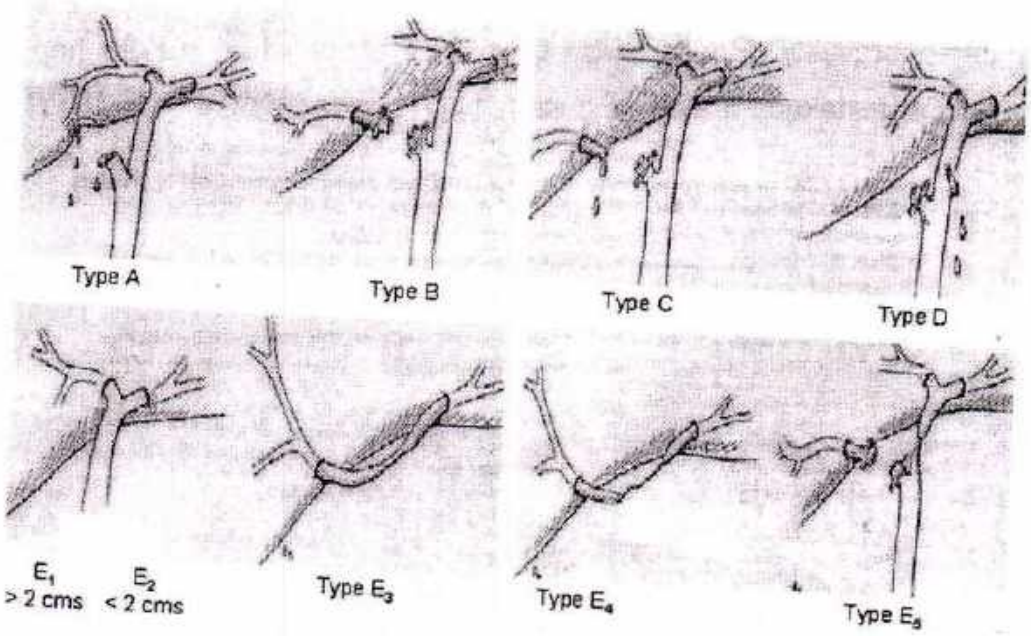
The Strasberg classification for cbd injuries goes as follows:

Type A. Bile leak from a minor duct retaining continuity with the common bile duct.

Types B and C. Creation of discontinuity for part of the biliary tree. Ductal occlusion injuries are designated as type B and transactions without occlusion as type C.

Type D. Lateral injury to the major bile duct. These injuries are partial (i.e.50%).

Type E. Circumferential injury to the major bile duct. These injuries are further divided into five types (E1 to E5). Types E1 to E4 are based on the level of injury, whereas E5 is a combination of common hepatic and right sectorial duct injury.



If cannulation of the CBD, rather than the cystic duct, occurs, during intra-operative cholangiography, the cholangiocatheter can be removed, and the ductotomy can be addressed by primary repair or by placing a T-tube, without the need for formal biliary reconstruction. A T-tube for large defects would allow the CBD to heal without stricture formation, and the tube can be removed nonoperatively several weeks after the cholecystectomy following cholangiography. The alternative scenario is complete transection of the CBD, a class III injury. In the absence of cholangiography, this transection is seldom recognized intraoperatively, typically presents postoperatively, and results in significant patient morbidity. Management requires an open bilioenteric anastomosis for repair; thus IOC has the potential to not only prevent bile duct injury, but also to mitigate its impact if injury does occur.[8]

Studies suggest that near infrared imaging with ICG provides a good overall visualization of the cystic, common bile, common hepatic ducts and the cystic duct junction with CBD prior to and following the dissection of Calot's triangle as proven by Vlek et al in their study in 2016.[17]

In their study in 2015, Dieuwertje et al found no significant difference between conventional laparoscopic cholecystectomy and cholecystectomy using near infrared imaging at critical view of safety

but with ICG , cystic duct was identifies significantly earlier with the NIR camera, where they used ICG injection at a dose of 0.05 mg/kg administered 1-2 hours prior to surgery.[18]

Gangemi et al reported in their study that the use of ICG during laparoscopic cholecystectomy was associated with a significant reduction in the rate of conversion from laparoscopic to open cholecystectomy.[19]

This visualization requires pre-operative injection with ICG in order for it to accumulate in the biliary system. The standard dose for this can vary depending upon the time interval between injection and surgery. In their study vlek et al, used either 2.5 mg standard dose of 0.05mg/kg dosage administered anywhere between one hour prior to anaesthesia to just after administration of anaesthesia.[17]

In a study by tsutsui et al, wherein they assessed intra-operative cholangiography with ICG by means of luminance intensity ratios between various structures of the hepatobiliary system and also the visibility of the gall bladder, cystic duct and CBD. They found the proportion of cases in which two or more evaluators classified the visibility of the gallbladder and bile duct as grade A first increased in the 12 hour study group, reached a peak in the 15 hour group and then decreased from then on and thus concluded that the best timing for administration of ICG is 15 hours prior to surgery when given at a standard dose of 25 mg.[20]

Zarrinpar et al in 2016 reported on the dose and timings of ICG administration for intra-operative cholangiography and concluded that a dose of 0.25 mg/kg administered at least 45 minutes prior to surgery facilitates intraoperative anatomical identification.[21]

The major limitation of fluorescent cholangiography lies in the limited ability of near infrared light to penetrate tissues (To a depth of 5-10mm).[2]

Another limitation to this intra-operative imaging technique is that it does not help inidentification of CBD stones.[9]

6.3 AIMS AND OBJECTIVES OF THE STUDY

To study :

1. Feasibility and safety of using ICG in lap. Cholecystectomy.
2. Post-operative outcome in patients undergoing lap. Cholecystectomy with ICG.
3. Timing of ICG administration for near infrared imaging in lap. Cholecystectomy.

7. MATERIALS AND METHODS

7.1 Source of Data

The study will be conducted among the patients admitted to the department of general surgery, Dayanand Medical College and hospital, Ludhiana.

7.2 METHOD OF COLLECTION OF DATA

Information shall be collected through pre-designed proforma for each patient that has been chosen to be a part of the study with detailed history, clinical examination and complete investigational work-up.

INCLUSION CRITERIA-

1. Patients undergoing lap. Cholecystectomy for any indication.
2. Patients with pre-operative imaging of the gall bladder using ultrasound or MRCP.

EXCLUSION CRITERIA-

1. History of previous intervention (cholecystostomy).
2. Patients with co-morbidities that rule out the possibility of laparoscopic surgery.

METHODS OF COLLECTION

The study will be conducted on patients undergoing laparoscopic cholecystectomy with the usage of indocyanine green dye and near-infrared camera imaging for visualization of the hepatobiliary system. The candidates for the study will be selected based on pre-op imaging investigations.

SAMPLE SIZE: TIME BOUND STUDY.

FOLLOW-UP PERIOD: Upto discharge from the hospital.

DURATION OF STUDY: July 2020 to December 2021

OUTCOME

To find out the feasibility, safety and outcomes of laparoscopic cholecystectomy performed with usage of indocyanine green dye by means of assessment of operation time, bile duct or vascular injury, infection, need for repeat procedure/intervention.

STATISTICAL ANALYSIS

Data will be described in the terms of range, mean +/- standard deviation, median, frequencies(number of cases) and relative frequencies(percentages) as appropriate. Comparison of quantitative variables will be done using paired t-test. A probability value of less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS ver. 21.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

1. ROUTINE INVESTIGATIONS INCLUDING HAEMOGRAM, PT/INR, LFT AND RFT.
2. USG WHOLE ABDOMEN.

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

ATTACHED HEREWITH

8. LIST OF REFERENCES

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PROFORMA

PLACE: DMC&H, LUDHIANA

DATE:

TIME:

DEMOGRAPHIC DETAILS:

NAME: AGE : SEX:

MRD NO. :

DATE OF ADMISSION:

DATE OF DISCHARGE:

CLINICAL DETAILS

CHIEF COMPLAINTS:

HOPI:

1. H/O PAIN ABDOMEN : Y/N
2. H/O VOMITING/NAUSEA : Y/N
3. H/O LOSS OF APPETITE : Y/N
4. H/O FEVER : Y/N
5. H/O JAUNDICE: Y/N
6. H/O RECURRENCE : Y/N
7. H/O LOOSE STOOLS : Y/N
8. H/O CONSTIPATION : Y/N
9. H/O IODINE ALLERY : Y/N

RISK FACTORS/CO-MORBIDITIES:

1. DIABETES MELLITUS : Y/N
2. HYPERTENSION : Y/N
3. ALCOHOLISM : Y/N
4. CLD: Y/N
5. CKD : Y/N
6. THYROID DISEASE: Y/N
7. MALIGNANCY : Y/N
8. CARDIAC DISEASE : Y/N

Signature of Candidate **Signature of Supervisor**

9. ANY OTHER:

EXAMINATION :

GENERAL PHYSICAL EXAMINATION:

BP: HR: RR: SpO2:

TEMPERATURE

GCS

SYSTEMIC EXAMINATION :

PER ABDOMEN :

DIFFUSE TENDERNESS : Y/N

LOCALIZED TENDERNESS : Y/N

DISTENSION:

PALPABLE LUMP :

REBOUND TENDERNESS:

RISE OF TEMPERATURE:

INVESTIGATIONS:

1. TLC :
2. HAEMOGLOBIN :
3. TOTAL BILIRUBIN :
4. DIRECT BILIRUBIN :
5. ALP :
6. TOTAL PROTEIN :
7. ALBUMIN :
8. SERUM ELECTROLYTES(SODIUM/POTASSIUM/CHLORIDE):
9. PT/INR:
10. USG ABDOMEN: Y/N
11. IMAGING FINDINGS :
12. MRCP : Y/N
13. CT ABDOMEN : Y/N

INTRA-OP FINDINGS:

1. TECHNIQUE USED

Signature of Candidate **Signature of Supervisor**

a. NUMBER OF PORTS : 3/4

b. LOCATION OF PORTS:

i. UMBILICAL : Y/N

ii. EPIGASTRIC : Y/N

iii. RIGHT HYPOCHONDRIUM : Y/N

iv. RIGHT LUMBAR : Y/N

c. TIMING OF ADMINISTRATION:

i. 1 HOUR PRIOR TO INDUCTION : Y/N

ii. 30 MINUTES PRIOR TO INDUCTION : Y/N

iii. 15 MINUTES PRIOR TO INDUCTION : Y/N

2. ADVERSE REACTION TO ICG: Y/N

3. TIMING OF FIRST VISUALIZATION OF GALL BLADDER:

4. TIMING OF FIRST VISUALIZATION OF CYSTIC DUCT:

5. TIMING OF FIRST VISUALIZATION OF CBD :

6. CONVERSION TO OPEN PROCEDURE: Y/N

7. BLOOD LOSS IN SURGERY :

a. <500 ML : Y/N

b. >500 ML : Y/N

8. DURATION OF SURGERY :

POST-OP COMPLICATIONS:

1. HEMATOMA : Y/ N

2. CYSTIC DUCT INJURY : Y/N

3. CBD INJURY :

A. PRESENT : Y/N

B. CLASS (AS PER STRASSBERG CLASSIFICATION):

4. CYSTIC ARTERY INJURY :Y/N

Signature of Candidate **Signature of Supervisor**

CERTIFICATE OF DEPARTMENTAL CLEARANCE

This is to certify that the plan of thesis entitled **"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY"** has discussed in the Department of Surgery and approved by whole of the faculty of the department. The plan writing is satisfactory.

Supervisor

Dr. Jaspal Singh
Professor & Head
Department of Surgery
DMCH, Ludhiana

Co-Supervisor

Dr. Sanjeev K. Singla
Professor
Department of Surgery
DMCH, Ludhiana

Head of the Department

Dr. Jaspal Singh
Professor & Head
Department of Surgery
DMCH, Ludhiana

DAYANAND MEDICAL COLLEGE & HOSPITAL,
LUDHIANA

Ref. No. DMCH/ Dated:

TO WHOM IT MAY CONCERN

I shall carry out the study **"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY"** meticulously and shall maintain the records for 5 years after the submission of thesis and present them to any competent authority as and when required. The following documents will be preserved:

1. List of enrolled patients with identification details
2. Consent forms of all the enrolled patients
3. Proforma of each patient with verifiable details, individually signed by supervisor.

Dr. Anubhavv Gupta
P.G. Resident
Dept. of Surgery
DMC & Hospital, Ludhiana

DAYANAND MEDICAL COLLEGE & HOSPITAL
LUDHIANA

Ref. No: DMCH/ Dated :

TO WHOM IT MAY CONCERN

Certified that the study entitled **"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY"** involves only such investigations and / or treatment, which are relevant in the management of patients and has no extra cost implications to the patient.

Name of candidate: Dr. Anubhavv Gupta

Supervisor: Dr. Jaspal Singh

Co-Supervisor(s): Dr. Sanjeev K. Singla

Signature of candidate

Signature of Supervisor

CERTIFICATE

We hereby certify that the informed patient consent form and its translation and back translation to Hindi and Punjabi are accurate to the best of our knowledge and satisfaction.

Supervisor

Dr. Jaspal Singh
Professor & Head
Department of Surgery
DMCH, Ludhiana

Co-Supervisor

Dr. Sanjeev K. Singla
Professor
Department of Surgery
DMCH, Ludhiana

Dr. Anubhavv Gupta
P.G. Resident
Dept. of Surgery
DMC & Hospital, Ludhiana

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....

.....am willing to participate in the study **"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

Name:

.....
Signature of the patient

Signature of Candidate

Signature of Supervisor

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य "**EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY**" में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____

गवाह के हस्ताक्षर

नाम:

_____

रोगी के हस्ताक्षर/अंगूठे का निशान

नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"EVALUATION OF THE ROLE OF INDOCYANINE GREEN IN LAPAROSCOPIC CHOLECYSTECTOMY" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ